OLYMPUS®

INSTRUCTIONS

EVIS EXERA ULTRASONIC BRONCHOFIBERVIDEOSCOPE

OLYMPUS BF TYPE **UC160F-OL8**

CAUTION : Balloons Used with This Product Contain Natural Rubber Latex, Which May Cause Allergic Reactions.

USA: CAUTION: Federal law restricts this device to sale by or on the order of a physician.	CE 0197

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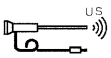
Symbols

The meaning(s) of the symbol(s) shown on the package, the back cover of this instruction manual and/or this instrument are as follows:

	Refer to instructions.
	Caution
	TYPE BF applied part
	Serial number
IPX7	Ingress protection rating (except for connectors)
	Lock the ultrasonic connector
	Release the ultrasonic connector
	Ultrasonic endoscope
	Single use only
	Do not resterilize
	Use by (expiration date)
	Sterilized using ethylene oxide
	Sterilization lot number
	Lot number

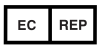
Keep away from sunlight

Keep dry

Do not use if package is damaged

Contains or Presence of Natural Rubber Latex

Manufacturer



Authorized representative in the European Community

Important Information — Please Read Before Use

Intended use

This instrument has been designed to be used with an Olympus compact endoscopic ultrasound center, video system center, light source, documentation equipment, video monitor, EndoTherapy accessories and other ancillary equipment.
This instrument is designed for endoscopic real-time ultrasonic imaging, ultrasound guided needle aspiration and other endoscopic procedures within the airways and trancheobronchial tree.
Do not use this instrument for any purpose other than its intended use.

Instruction manual

This instruction manual contains essential information on using this instrument safely and effectively. Before use, thoroughly review this manual and the manuals of all equipment which will be used during the procedure and use the equipment as instructed.
Keep this and all related instruction manuals in a safe, accessible location.
If you have any questions or comments about any information in this manual, please contact Olympus.

User qualifications

The operator of this instrument must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique. This manual, therefore, does not explain or discuss clinical endoscopic procedures.

Instrument compatibility

Refer to the “System chart” in the Appendix to confirm that this instrument is compatible with the ancillary equipment being used. Using incompatible equipment can result in patient injury and/or equipment damage.

This instrument complies with EMC standard for medical electrical equipment; edition 2 (IEC 60601-1-2: 2001). However, when connected with an instrument that complies with EMC standard for medical electrical equipment; edition 1 (IEC 60601-1-2: 1993), the whole system complies with edition 1.

Reprocessing before the first use/reprocessing and storage after use

This instrument was not cleaned, disinfected or sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions given in Chapter 7, “Cleaning, Disinfection and Sterilization Procedures”.

After using this instrument, reprocess and store it according to the instructions given in Chapters 5, “Reprocessing: General Policy” through 9, “Storage and Disposal”. Improper and/or incomplete reprocessing or storage can present an infection control risk, cause equipment damage or reduce performance.
The balloons are disposable, and are intended for a single use only; a new one must be used for each patient. Do not attempt to reuse or re-sterilize a balloon.

Prohibition of improper repair and modification

Never repair by persons other than Olympus-qualified technicians or modify the instrument, as this may result in injury of the patient or operator as well as equipment damage to the equipment.
Some problems that appear to be malfunctions may be correctable by referring to Chapter 10, “Troubleshooting”. If the problem cannot be resolved using the information in Chapter 10, contact Olympus.

Signal words

The following signal words are used throughout this manual:

WARNING

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.

NOTE

Indicates additional helpful information.

Warnings and cautions

Follow the warnings and cautions given below when handling this instrument. This information is to be supplemented by the warnings and cautions given in each chapter.

WARNING

- This endoscope has a “forward oblique” view. There is a difference between the direction of view and the insertion direction of the endoscope. The insertion direction appears in the lower portion of the endoscopic view, and the visible area in that direction is limited. Always view the endoscopic image carefully, and insert the endoscope prudently. Otherwise, patient injury may occur.
- Never perform angulation control, perform suction, insert or withdraw the endoscope’s insertion tube without viewing the endoscopic image. Patient injury can result.
- Do not touch the light guide of the endoscope connector immediately after removing it from the light source because it is extremely hot. Operator or patient injury can result.
- Regardless of the flexibility of the endoscope’s insertion tube, do not attempt to bend it with excessive force. Otherwise, patient injury could result.
- This endoscope is not intended for fetal use.
- Clean and disinfect or sterilize the endoscope as described in Chapter 5 through 8 of this manual, before use.

- Never perform high-suction continuously. Patient injury can result.
- Never tie the elastic opening of both sides of the balloon with a thread. This may cause the balloon to rupture or come off the distal end of the endoscope when inflating it excessively. This can result in patient injury.
- Never inflate the balloon to a diameter of more than 20 mm when using the endoscope in the trachea. This could result in suffocation of the patient.
- Never withdraw the endoscope while the balloon is still inflated. Otherwise, the balloon may burst or come off the distal end of the endoscope. If the balloon cannot be deflated, insert the channel cleaning wire into the irrigation port. Using slow, short strokes, carefully feed the wire to remove debris.
- When withdrawing the endoscope, make sure that the balloon is completely deflated, using the ultrasonic image and endoscopic field of view. Withdrawing the endoscope while the balloon is inflated could result in patient injury.
- If any irregularity in the ultrasound image is observed, turn the ultrasound center OFF immediately. Continued ultrasound radiation will cause the distal end to become hot and could cause operator and/or patient burns.

CAUTION

- Do not pull the universal cord. The endoscope connector will be pulled out from the output socket of the light source and the endoscopic image will not be visible.
- Do not coil the insertion tube, universal cord or ultrasonic cable into a diameter of less than 12 cm. Equipment damage can result and/or the ultrasonic image will be abnormal.
- Do not apply shock to the distal end of the insertion tube, particularly the ultrasonic transducer and the objective lens surface at the distal end. Visual abnormalities may result.
- Do not twist or bend the bending section with your hands. Equipment damage may result.
- Do not squeeze the bending section forcefully. The covering of the bending section may stretch or break and cause water leaks.
- The cover of the irrigation port part cannot be removed. Equipment damage can result.

- Do not hit or bend the electrical contacts on the endoscope connector. The connection to the light source may be impaired and faulty contact can result.
- Do not attempt to bend the endoscope's insertion tube with excessive force. Otherwise, the insertion tube may be damaged.
- Do not touch the electrical contacts in the ultrasonic connector. Equipment damage can result.
- Do not pull, twist or tightly coil the ultrasonic cable. Noise can develop in the ultrasonic image.
- To prevent unnecessary patient exposure to ultrasonic radiation, follow the 'as-low-as-reasonably achievable' (ALARA) principle when using Olympus ultrasonic equipment. Freeze the image whenever you are not actively viewing the "live" ultrasonic image. When the equipment is in the FREEZE mode, no ultrasonic energy is emitted.
- Electromagnetic interference may occur on this instrument near equipment marked with the following symbol or other portable and mobile RF (Radio Frequency) communications equipment such as cellular phones. If electromagnetic interference occurs, mitigation measures may be necessary, such as reorienting or relocating this instrument, or shielding the location.

NOTE

It is highly desirable that a backup endoscope be available to continue clinical procedures in case of a malfunction.

Examples of inappropriate handling

Details on clinical endoscopic technique are the responsibility of trained specialists. Patient safety in endoscopic examinations and endoscopic treatment can be ensured through appropriate handling by the physician and the medical facility. Examples of inappropriate handling are given below.

- Over-insufflating the lumen may cause patient pain and/or perforation.
- Using improperly or incompletely reprocessed or stored instruments may cause patient cross-contamination and infection.
- Applying prolonged suction with the distal end in contact with the mucosal surface may cause bleeding or suction lesions.
- Inserting and using EndoTherapy accessories without a clear endoscopic image may cause patient injury.
- Patient injury may be caused by:
  - inserting or withdrawing the endoscope or applying suction without a clear endoscopic image
  - forcefully pulling or rotating the angulated bending section

The system limits the surface temperature of the transducer to 40°C. The surface temperature is limited by means of a power monitor protection circuit that protects against the electrical current exceeding established specifications. If the power monitor protection circuit detects a current overload, the transducer shits off immediately, preventing over-heating of the surface.

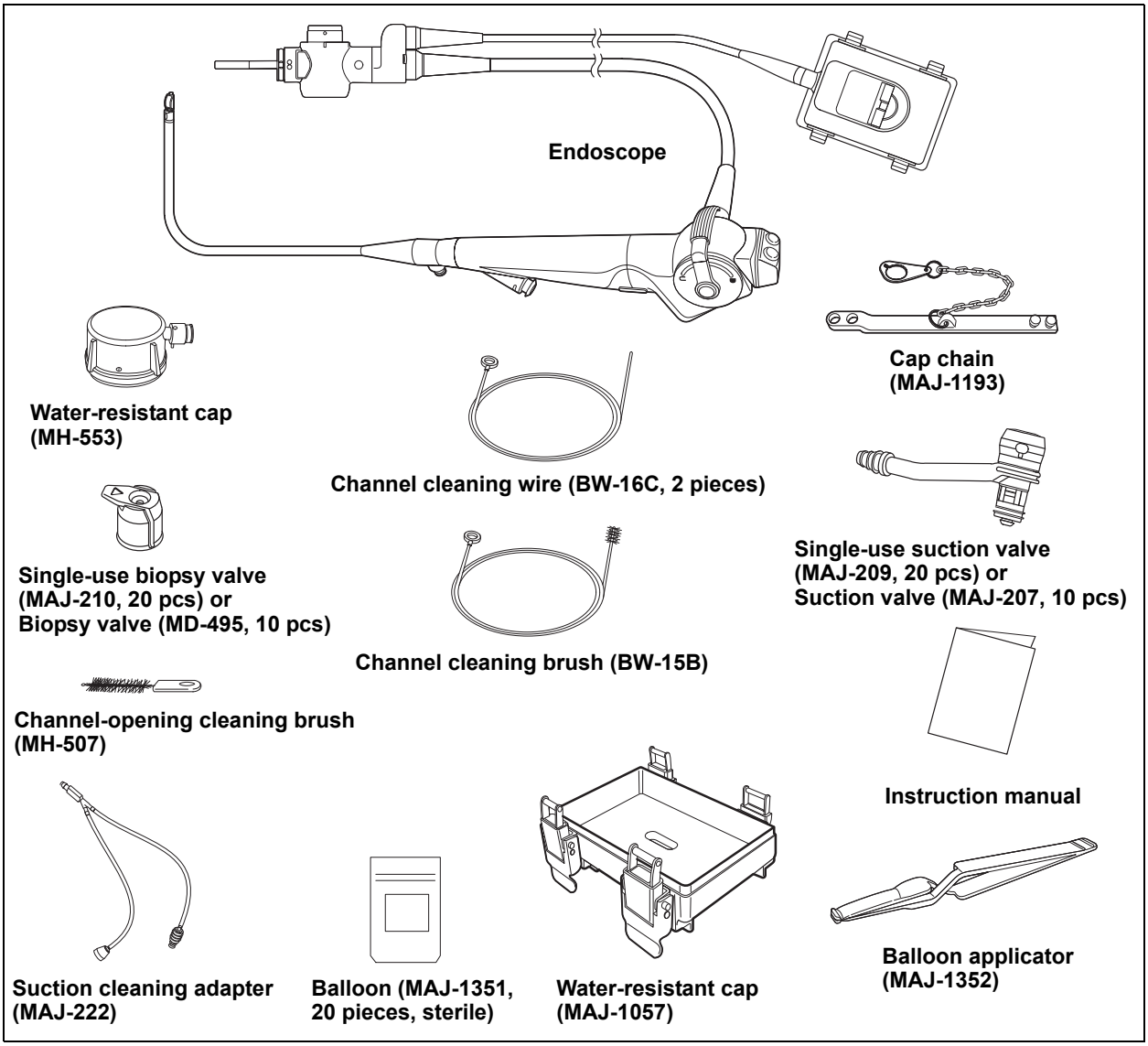
Natural rubber latex medical alert

Balloons used with this instrument contain natural rubber latex which may cause allergic reactions in some patients.
Do not use this instrument on a latex-sensitive patient.

Chapter 1 Checking the Package Contents

1.1 Standard components

Match all items in the package with the components shown below. Inspect each item for damage. If the instrument is damaged, a component is missing or you have any questions, do not use the instrument; immediately contact Olympus. This instrument was not disinfected or sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions given in Chapter 7, “Cleaning, Disinfection and Sterilization Procedures”.

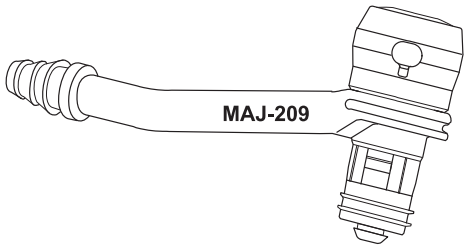

Endoscope
Water-resistant cap (MH-553)
Cap chain (MAJ-1193)
Channel cleaning wire (BW-16C, 2 pieces)
Single-use suction valve (MAJ-209, 20 pcs) or Suction valve (MAJ-207, 10 pcs)
Single-use biopsy valve (MAJ-210, 20 pcs) or Biopsy valve (MD-495, 10 pcs)
Channel cleaning brush (BW-15B)
Channel-opening cleaning brush (MH-507)
Instruction manual
Balloon applicator (MAJ-1352)
Suction cleaning adapter (MAJ-222)
Balloon (MAJ-1351, 20 pieces, sterile)
Water-resistant cap (MAJ-1057)

1.2 Optional components

The items listed below are optional, and may be possible to purchased from Olympus.

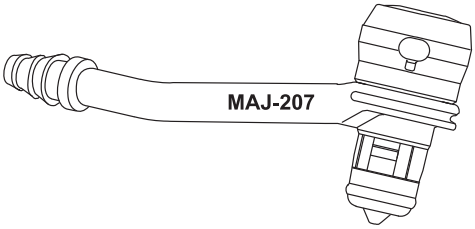
Suction valve

❍ For the U.S.A. only



Single-use suction valve (MAJ-209)

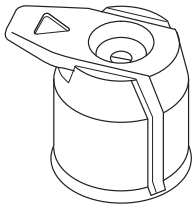
❍ For countries other than the U.S.A.



Suction valve (MAJ-207)

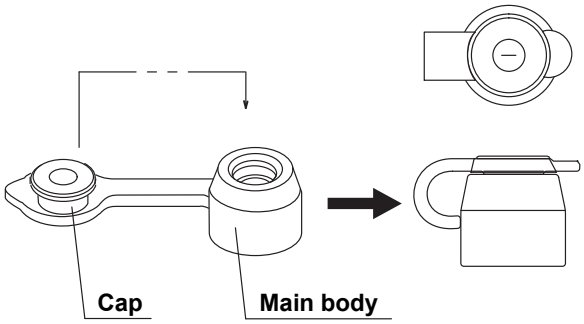
Biopsy valve

❍ For the U.S.A. and Europe



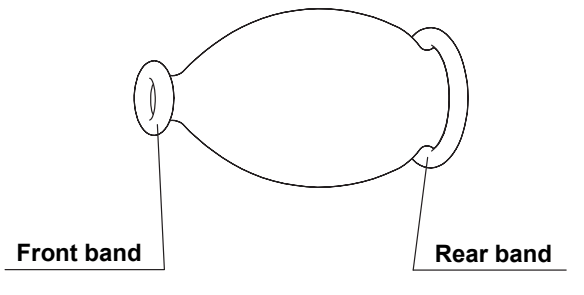
Single-use biopsy valve (MAJ-210)

❍ For countries other than the U.S.A. and Europe



Biopsy valve (MD-495)

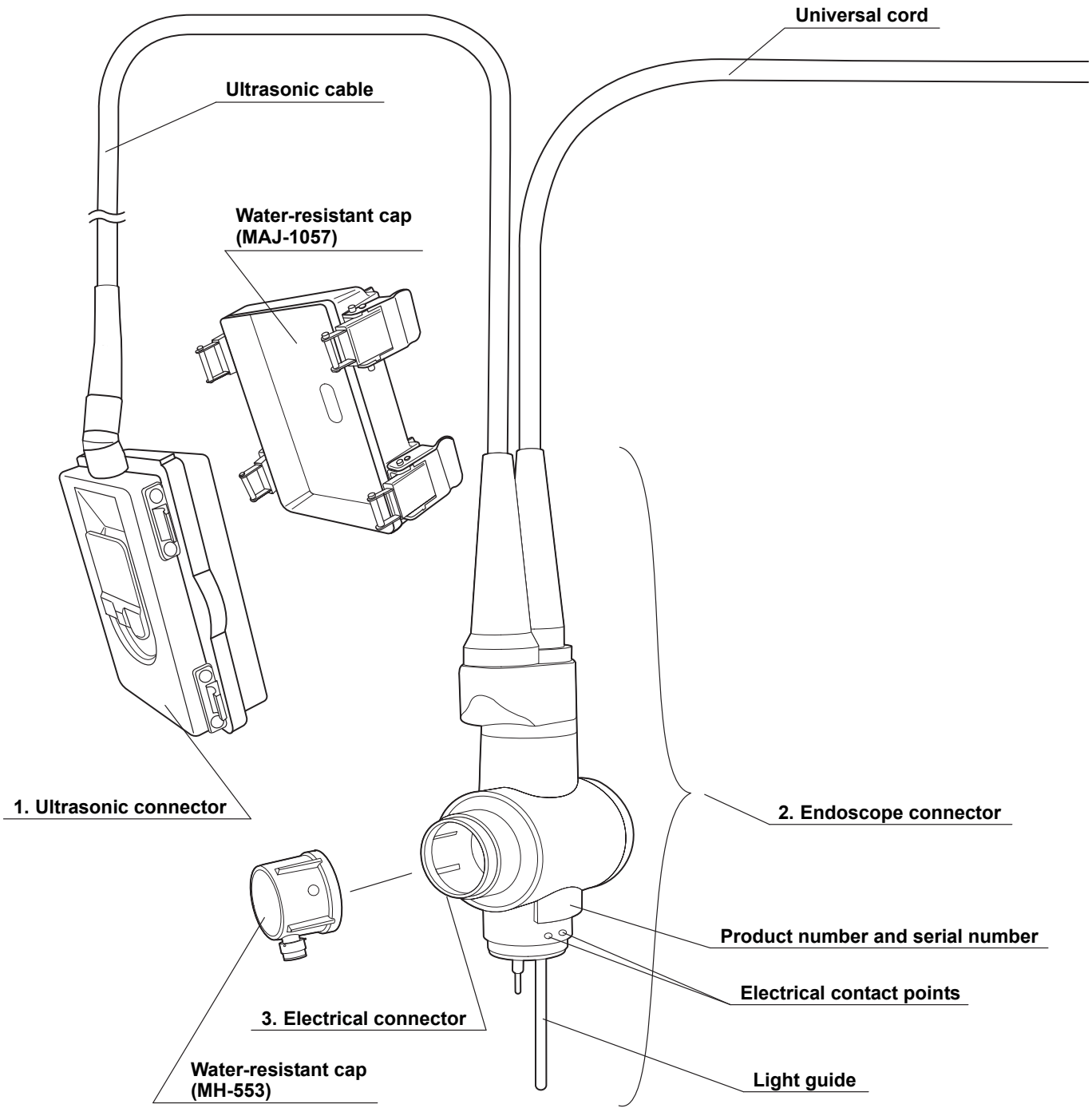
Balloon

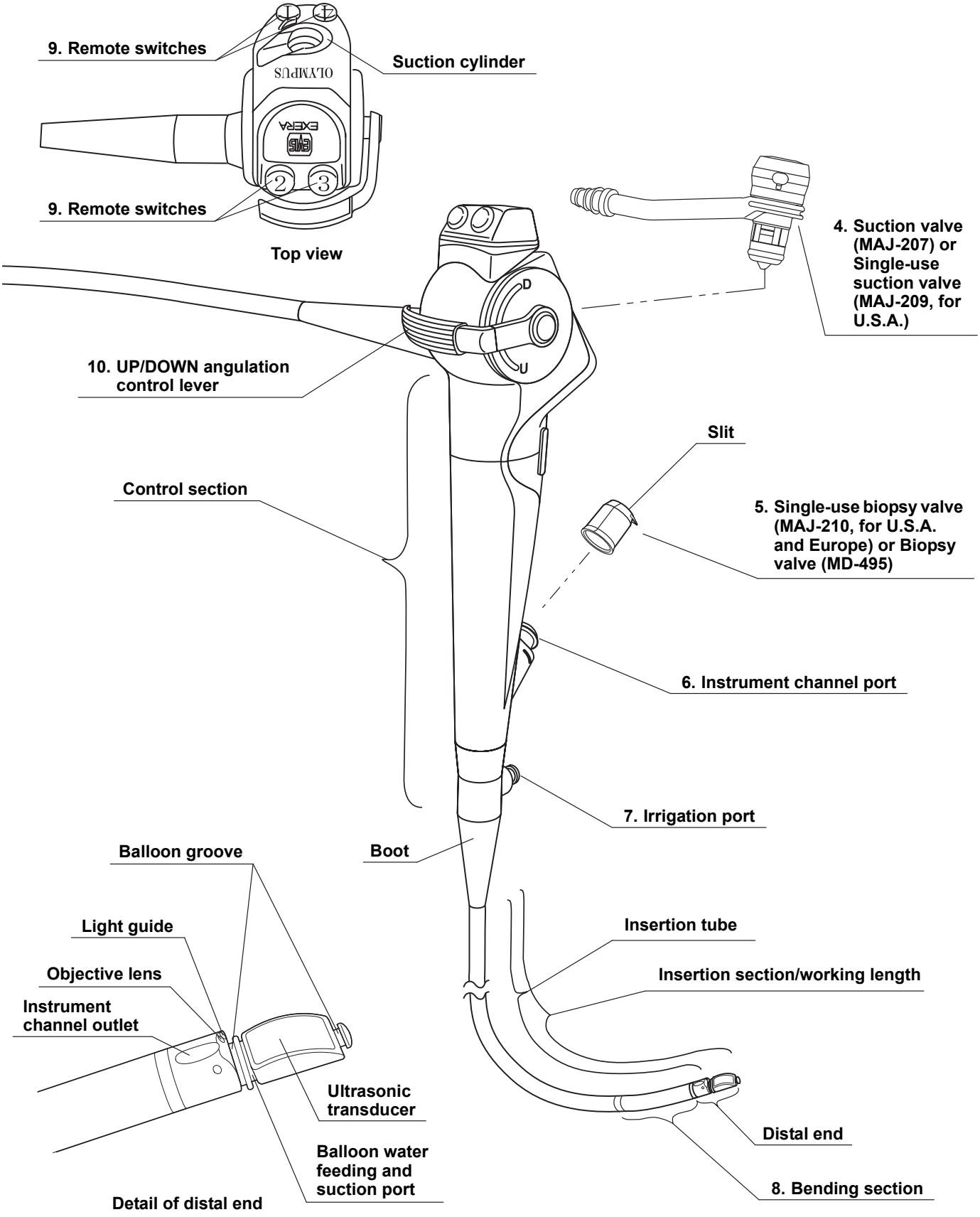


Balloon (MAJ-1351)

Chapter 2 Instrument Nomenclature and Specifications

2.1 Nomenclature




9. Remote switches
Suction cylinder
OLYMPUS
EXERA
9. Remote switches
Top view
4. Suction valve (MAJ-207) or Single-use suction valve (MAJ-209, for U.S.A.)
D
U
10. UP/DOWN angulation control lever
Slit
Control section
5. Single-use biopsy valve (MAJ-210, for U.S.A. and Europe) or Biopsy valve (MD-495)
6. Instrument channel port
7. Irrigation port
Balloon groove
Boot
Light guide
Insertion tube
Objective lens
Insertion section/working length
Instrument channel outlet
Ultrasonic transducer
Distal end
Balloon water feeding and suction port
8. Bending section
Detail of distal end

2.2 Endoscope functions

1. **Ultrasonic connector**
   The ultrasonic connector connects the endoscope to the endoscopic ultrasound center.
2. **Endoscope connector**
   The endoscope connector connects the endoscope to the output socket of the light source and transmits light from the light source to the endoscope.
3. **Electrical connector**
   The electrical connector connects the EVIS video system center via the videoscope cable.
4. **Suction valve (MAJ-207) or Single-use suction valve (MAJ-209, for U.S.A.)**
   The suction valve is depressed to activate suction. The valve is also used to remove any fluid or debris adhering to the objective lens.

WARNING

- Use of the suction valve (MAJ-207) is not recommended for more than 6 procedures.
- The single-use suction valve (MAJ-209) is designed for a single use only. Do not reuse or attempt to resterilize it.

5. **Single-use biopsy valve (MAJ-210, for U.S.A. and Europe) or Biopsy valve (MD-495)**
   Accessories may be inserted through the slit in this valve. When using the single-use biopsy valve (MAJ-210), a syringe may be inserted for the introduction of fluids.

WARNING

The single-use biopsy valve (MAJ-210) is designed for a single use only. Do not attempt to reuse or resterilize it.

6. **Instrument channel port**
   The instrument channel port functions as:
   - channel for insertion of EndoTherapy accessories.
   - suction channel
   - fluid feed channel (from a syringe via the biopsy valve)
7. **Irrigation port**
   Connects an extension tube, a three-way stopcock or a syringe to feed water in the balloon or suck water from the balloon through the balloon channel.

8. **Bending section**
The bending section moves the distal end of the endoscope when the UP/DOWN angulation control lever is operated.

9. **Remote switches 1 to 4**
The functions of remote switches 1 to 4 can be selected on the EVIS video system center. When selecting the functions, refer to the instruction manual for the EVIS video system center.

10. **UP/DOWN angulation control lever**
When the lever is moved in the “U” direction, the bending section moves UP; when the lever is moved in the “D” direction, the bending section moves DOWN.

2.3 Specifications

NOTE

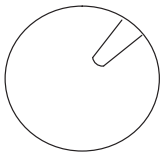
- This endoscope differs from a general videoscope. The endoscopic image is transmitted to the control section by the image guide and converted into an electrical signal with the CCD in the control section.
- Only a limited type of EndoTherapy accessories are compatible with this endoscope compared with a general ø 2.0 mm channel endoscope. This is because it has a unique shaped instrument channel outlet. Refer to the "System chart" in the Appendix to confirm the detail about the compatible EndoTherapy accessories.

Operating environment

Operating environment	**Ambient temperature**	10 – 40°C (50 – 104°F)
	Relative humidity	30 – 85%
	Air pressure	700 – 1060 hPa (0.7 – 1.1 kgf/cm^2) (10.2 – 15.4 psia)

Specifications

❍ Endoscope functions

Optical system	**Field of view**	80°
	Direction of view	35° Forward oblique
	Depth of field	2 – 50 mm
Insertion tube	**Distal end outer diameter**	ø 6.9 mm
	Insertion tube outer diameter	ø 6.2 mm
	Working length	600 mm
Instrument channel	**Channel inner diameter**	ø 2.0 mm
	Minimum visible distance	5 mm
	Direction from which EndoTherapy accessories enter and exit the endoscopic image	
Bending section	**Angulation range**	UP 120°, DOWN 90°
Total length		890 mm

Ultrasonic functions

Display mode	B-mode, CPD-mode
Scanning method	Electrical curved linear array
Scanning direction	Parallel to the insertion direction
Frequency	7.5 MHz
Scanning range	50°
Contacting method	Balloon method, Direct contact method
Transducer surface max. temperature	43°C >

Medical Devices Directive	CE 0197	This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class II a
EMC	**Applied standards; IEC 60601-1-2: 2001 IEC 60601-2-37: 2007**	This instrument complies with the standards listed in the left column. CISPR 11 of emission: Group 1, Class A This instrument complies with the EMC standard for medical electrical equipment; edition 2 (IEC 60601-1-2: 2001). However, when connecting to an instrument that complies with the EMC standard for medical electrical equipment; edition 1 (IEC 60601-1-2: 1993), the whole system complies with edition 1.
Year of manufacture	**1<u>4</u>12345** ↑ └────────	The year of manufacture is the second digit of the serial number.
Degree of protection against electric shock		TYPE BF applied part
Ingress protection rating	**IPX7**	This instrument complies with the standards for medical electrical equipment: IEC 60601-1:1988 IEC 60601-2-37:2007.

Chapter 3 Preparation and Inspection

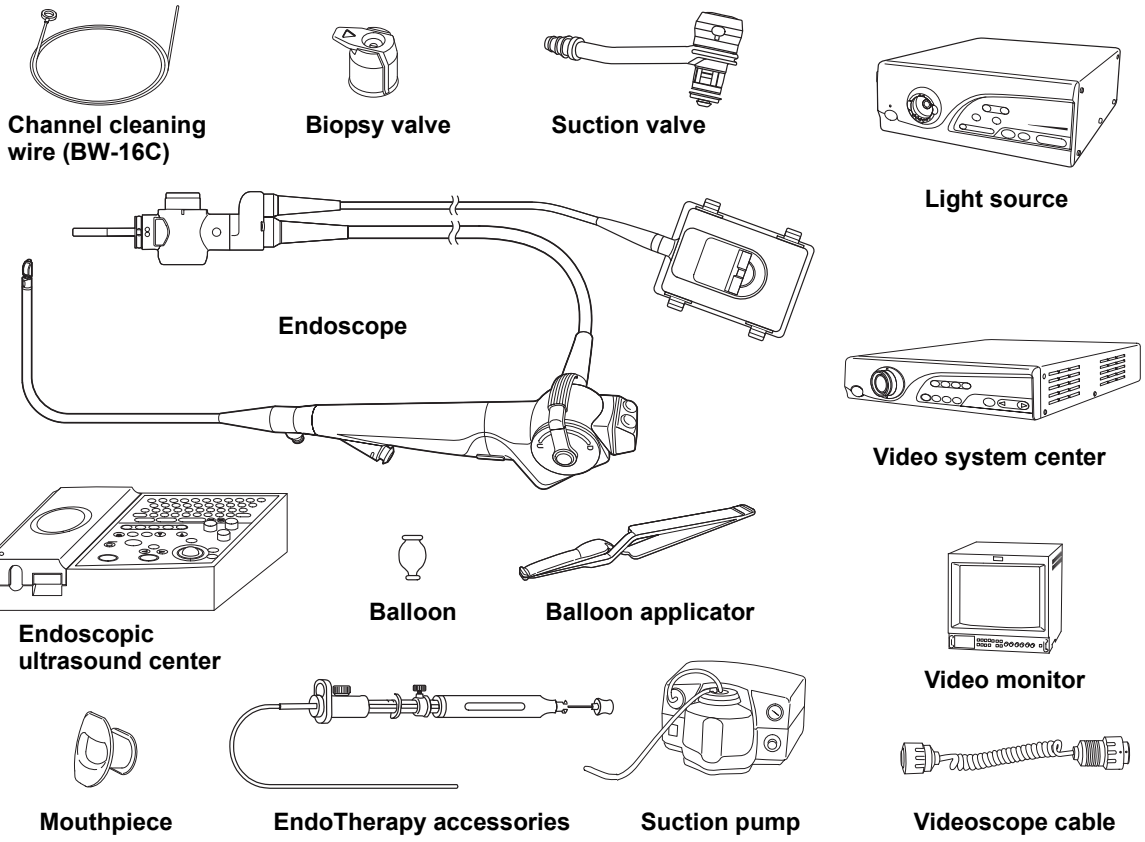
Before each case, prepare and inspect this instrument as instructed below. Inspect other equipment to be used with this instrument as instructed in their respective instruction manuals. Should the slightest irregularity be suspected, do not use this instrument and see Chapter 10, “Troubleshooting”. If the irregularity is still suspected after consulting Chapter 10, contact Olympus.
Damage or irregularity may compromise patient or user safety and may result in more severe equipment damage.

WARNING

- This instrument was not cleaned, disinfected or sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions given in Chapter 7, “Cleaning, Disinfection and Sterilization Procedures”.
- Using the instrument that is not functioning properly may compromise patient or operator safety and may result in more severe equipment damage.
- Do not pull the universal cord or the ultrasonic cable with excessive force when the endoscope is connected to the other equipment. Equipment damage could occur.

3.1 Preparation of the equipment

Prepare the equipment shown in Figure 3.1 (for compatibility, see the “System chart” in the Appendix) and personal protective equipment, such as eye wear, face mask, moisture-resistant clothing and chemical-resistant gloves, before each use. Refer to the respective instruction manuals for each piece of equipment.



- **Paper towels**
- **Trays**
- **Lint-free cloths**
- **Personal protective equipment**
- **3-way stopcock**
- **Syringe**
- **Extension tube**
- **Sterile de-aerated water**
- **Medical-grade, watersoluble lubricant**

Figure 3.1

3.2 Inspection of the endoscope

Clean and disinfect or sterilize the endoscope as described in Chapter 7 and 8 of this manual.

Inspection of the endoscope

1. Inspect the control section and the endoscope connector for excessive scratching, deformation or other irregularities.
2. Inspect the boot and the insertion tube near the boot for bends, twists or other irregularities.
3. Inspect the external surface of the entire insertion tube including the bending section and distal end for dents, bulges, swelling or other irregularities.
4. Holding the insertion tube gently with a hand, carefully run your fingertips over the entire length of the insertion tube in both directions. Inspect for any protruding objects or other irregularities (see Figure 3.2).

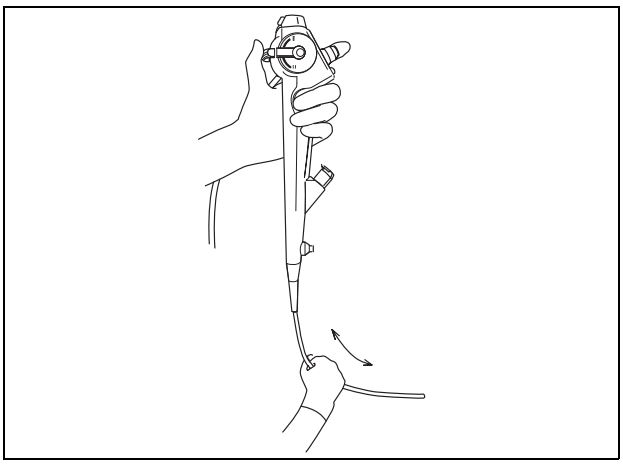


Figure 3.2

5. Inspect the covering of the bending section for sagging, swelling, cuts, holes or other irregularities.
6. Gently hold the midpoint of the bending section and a point 10 cm from the distal end. Push and pull gently to confirm that there is no play.
7. Inspect the objective lens and light guide at the distal end of the endoscope for dents, bulges, swelling or other irregularities.
8. Carefully inspect the distal end of the endoscope, especially around the ultrasonic transducer. Confirm that there are no flaws, cracks, scratches or any other irregularities.

Inspection of the bending mechanism

Perform the following inspection while the bending section is straight.

WARNING

If the movement of the UP/DOWN angulation control lever are not smooth, the bending mechanism may be abnormal. In this case, do not use the endoscope because it may be impossible to straighten the bending section in the middle of examination.

❍ Inspection for smooth operation

1. Turn the UP/DOWN angulation control lever slowly in each direction until it stops. Confirm that the bending section angulates smoothly and correctly and that maximum angulation can be achieved.
2. Turn the UP/DOWN angulation control lever slowly to its neutral position. Confirm that the bending section returns smoothly to an approximately straight condition.

3.3 Preparation and inspection of accessories

Clean and disinfect or sterilize the suction valve and the biopsy valve as described in the endoscope's companion reprocessing manual.

Inspection of the suction valves

WARNING

- Do not use the suction valve (MAJ-207) for more than six procedures.
- The single-use suction valve (MAJ-209) is supplied sterile and is intended for a single use only. Do not attempt to reuse or resterilize it.
  This could pose an infection-control risk or cause equipment damage.
- Do not use the single-use suction value (MAJ-209) after the expiration date displayed on the sterile package. Doing so may pose an infection control risk.
- The single-use suction valves (MAJ-209) is provided in sterile condition. Do not open the package until ready to use.

NOTE

Both suction valves (MAJ-207 and MAJ-209) are designed for use with BF-30, 40, 200, 240, 260 and 160 series endoscopes.

1. Inspect the sterile package for tears, inadequate sealing or water damage. If the sterile package shows any irregularities, the sterile condition of the instrument may have been compromised. Use a spare instead.
2. Confirm that the valve is not deformed or cracked (see Figures 3.3 and 3.4).
3. Confirm that the button can be pushed without excessive resistance.

   • Suction valve (MAJ-207)

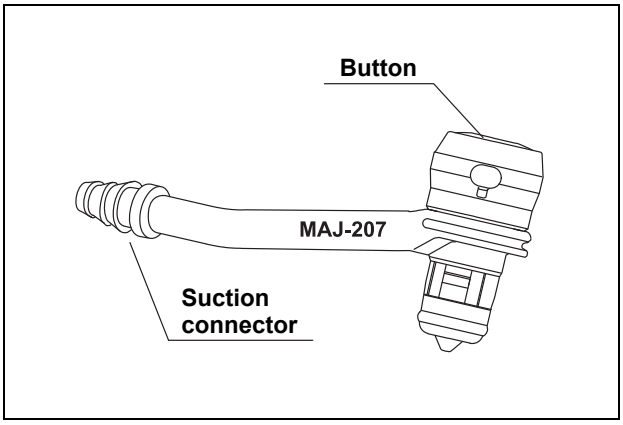


Figure 3.3

• Single-use suction valve (MAJ-209, for U.S.A.)

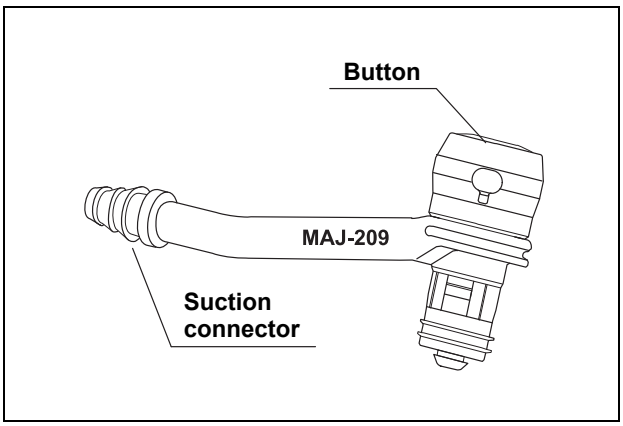


Figure 3.4

Inspection of the biopsy valves

WARNING

- The single-use biopsy valve (MAJ-210) is supplied sterile and is intended for a single use only. Do not attempt to reuse or resterilize it.
  This could pose an infection-control risk or cause equipment damage.
- Do not use the biopsy valve (MD-495) for more than six procedures.
- Do not use the single-use biopsy valve (MAJ-210) and the biopsy valve (MD-495) with the single use aspiration needle (NA-201SX-4022). Please use the single-use adapter biopsy valve (MAJ-1414), which is included in the needle set. And refer to the instruction manual of the single use aspiration needle (NA-201SX-4022).

CAUTION

The biopsy valve (MD-495) is subject to wear, and should be inspected before each use. Replace the biopsy valve with a new one if irregularities and/or excessive wear are detected. A damaged or deformed biopsy valve can reduce the efficacy of the endoscope's suction system and may cause patient debris to leak or spray from the endoscope and may result in infections.

NOTE

Both valves (MAJ-210 and MD-495) are designed for use with BF-30, 40, 200, 240, 260 and 160 series endoscopes.

❍ Single-use biopsy valve (MAJ-210, for U.S.A. and Europe)

Confirm that the biopsy valve is free from cracks, tears or deformation (see Figure 3.5).

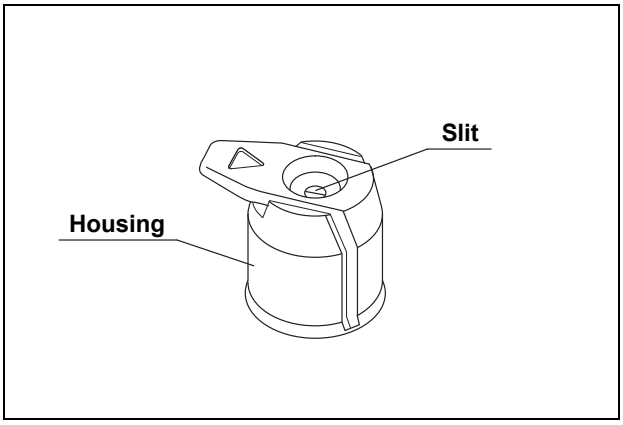


Figure 3.5

❍ Biopsy valve (MD-495)

1. Confirm that the biopsy valve is free from cracks, tears or deformation.
2. Attach the cap to the main body (see Figure 3.6).

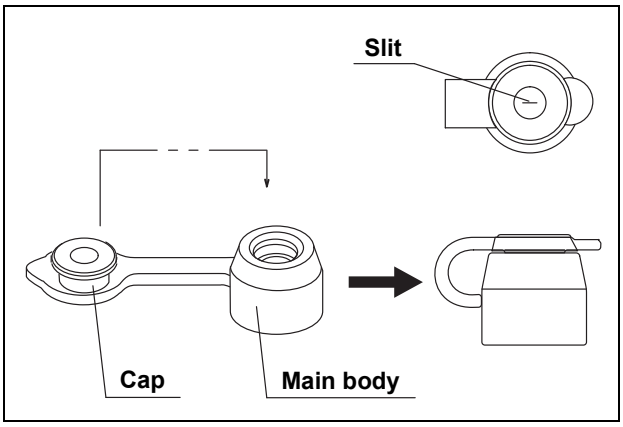


Figure 3.6

Inspection of the mouthpiece (MA-651, optional)

CAUTION

Do not use a mouthpiece that is damaged, deformed or reveals other irregularities. Doing so may cause patient injury and/or equipment damage.

NOTE

Placing the mouthpiece in the patient's mouth before the procedure prevents the patient from biting and/or damaging the endoscope's insertion tube.

1. Confirm that the mouthpiece is free from cracks, deformation or discoloration (see Figure 3.7).

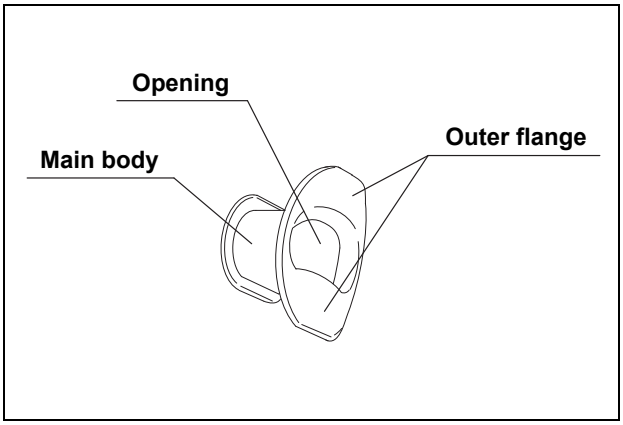


Figure 3.7

2. Using your fingers, check for excessive scratching or other irregularities on the surfaces of the mouthpiece (see Figure 3.7).

3.4 Attaching accessories to the endoscope

CAUTION

The suction valve do not require lubrication. Lubricants can cause swelling of the valve's seals, which will impair valve function.

Attaching the suction valve

1. Insert the suction valve (MAJ-207, MAJ-209) into the suction cylinder, then align the arm of the main body with the white mark on the endoscope (see Figure 3.8).
2. Press the top of the suction valve down with your finger until it clicks. Confirm that the suction valve is secure and operates smoothly.

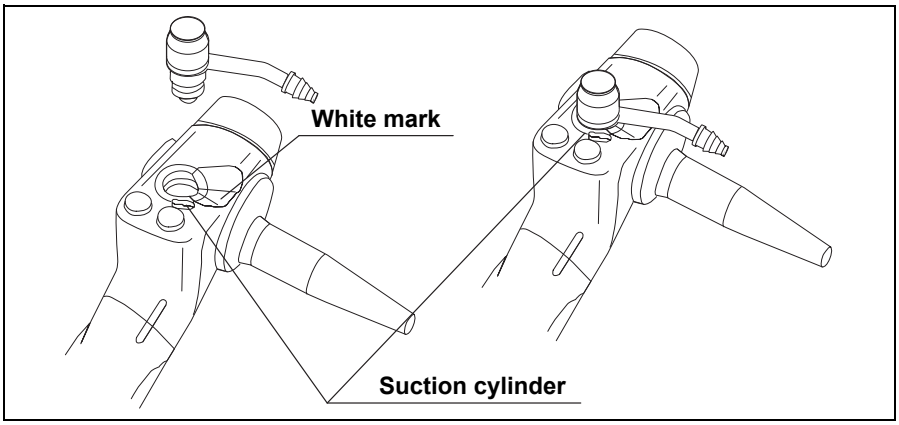


Figure 3.8

NOTE

Sometimes the suction valve will click before it is fully seated in the suction cylinder. Press on the suction valve down firmly with your finger to ensure that it is fully seated in the suction cylinder.

3. Connect the suction tube on the suction valve.

Attaching the biopsy valve

WARNING

If a biopsy valve is not properly connected to the instrument channel port, it can reduce the efficacy of the endoscope's suction system and may cause patient debris to leak or spray from the endoscope.

NOTE

At lower temperatures, the biopsy valve may become stiff and difficult to attach it. In this case, press it down more firmly to attach it.

Attach the biopsy valve (MAJ-210, MD-495) to the instrument channel port of the endoscope (see Figure 3.9). Confirm that the valve fits properly.

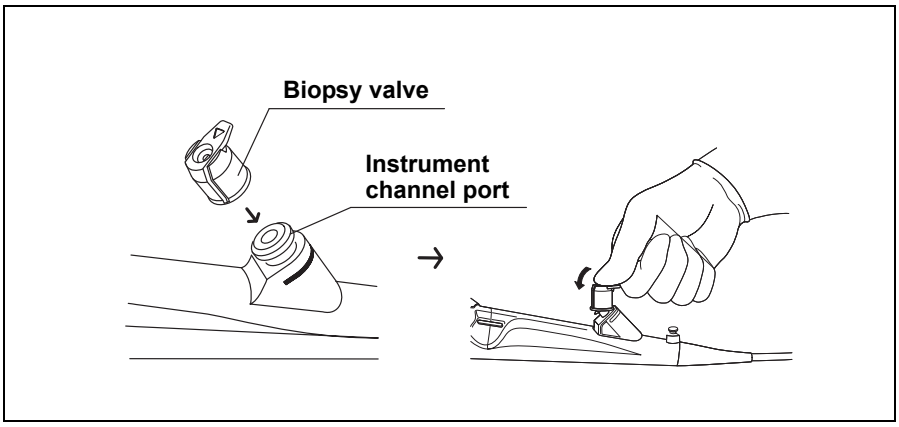


Figure 3.9

3.5 Inspection and connection of ancillary equipment

Inspection of ancillary equipment

Prepare and inspect the light source, endoscopic ultrasound center, video system center, video monitor, videoscope cable, suction pump and EndoTherapy accessories as described in their respective instruction manuals.

Connection of the endoscope and ancillary equipment

WARNING

Firmly connect the suction tube to the suction valve. If the suction tube is not attached properly, debris may drip from the tube and can present an infection control risk, damaged and/or reduce performance.

CAUTION

- The electrical contacts inside the ultrasonic connector may be damaged by handling. Do not touch the electrical contacts. If the electrical contacts are dirty, wipe the contacts with a soft and lint-free cloth.
- Do not open the flip cover of the ultrasound center with excessive force. Otherwise, the flip cover may break and could cause damage or injury.

1. If any ancillary equipment is ON, turn it OFF.
2. Insert the endoscope connector completely into the output socket of the light source.
3. Open the flip cover of the ultrasound center.

4. On the ultrasonic connector, pull the lever up and rotate it clockwise until it stops. The lever should be easy to move. Do not force the lever (see Figures 3.10 and 3.11).

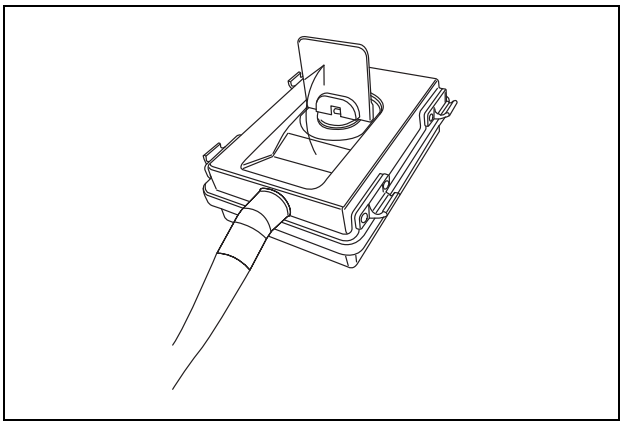


Figure 3.10

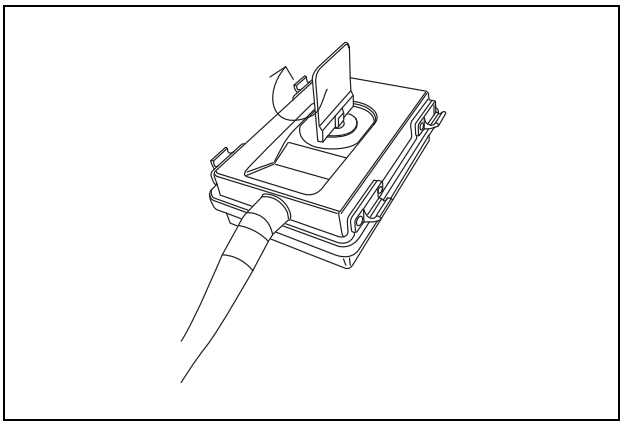


Figure 3.11

5. Align the ultrasonic connector with the receptacle on the socket of the compact endoscopic ultrasound center and insert it by pushing the ultrasonic connector into the receptacle of the compact endoscopic ultrasound center. The ultrasonic connector should be easy to insert. Do not force the ultrasonic connector (see Figures 3.12 and 3.13).

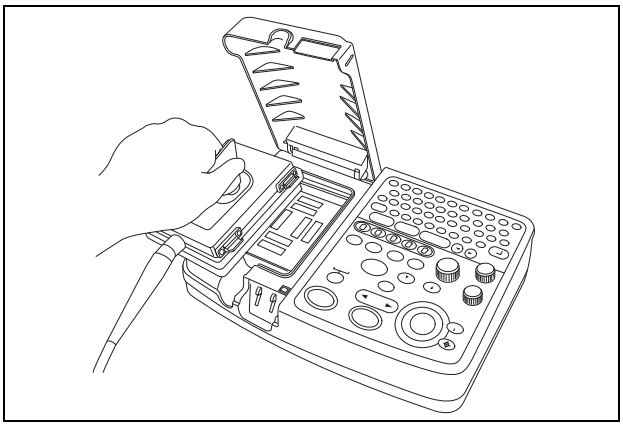


Figure 3.12

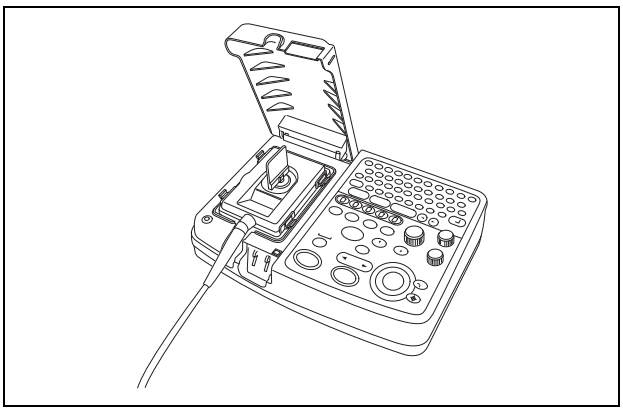


Figure 3.13

6. Turn the lever counterclockwise until it stops (see Figure 3.14).

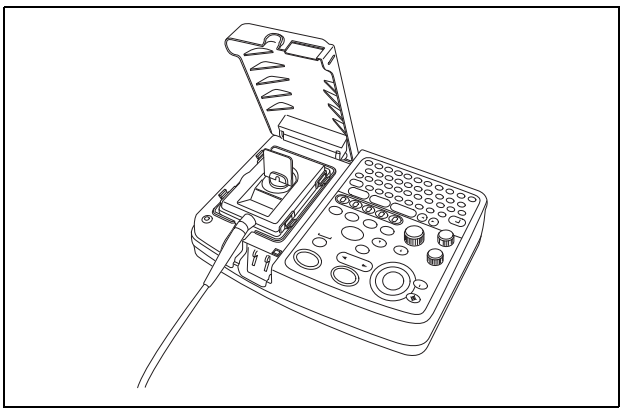


Figure 3.14

7. Press the lever down until it snaps into place, securing the ultrasonic connector to the system (see Figure 3.15).

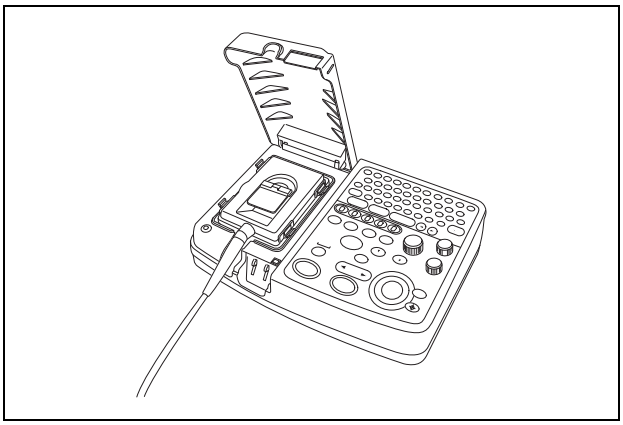


Figure 3.15

8. Close the flip cover of the compact endoscopic ultrasound center.

9. After confirming that the video system center is OFF, connect the videoscope cable 100 or the videoscope cable EXERA to the endoscope's electrical connector, following steps 10. to 12. below (see Figure 3.16).

10. Align the mark on the videoscope cable 100 or the videoscope cable EXERA with mark 1 on the electrical connector, and push it until it stops.

11. Turn the videoscope cable 100 or the videoscope cable EXERA clockwise until it stops.

12. Confirm that the mark on the videoscope cable 100 or the videoscope cable EXERA is aligned with mark 2 on the light source side of the endoscope's light guide connector.

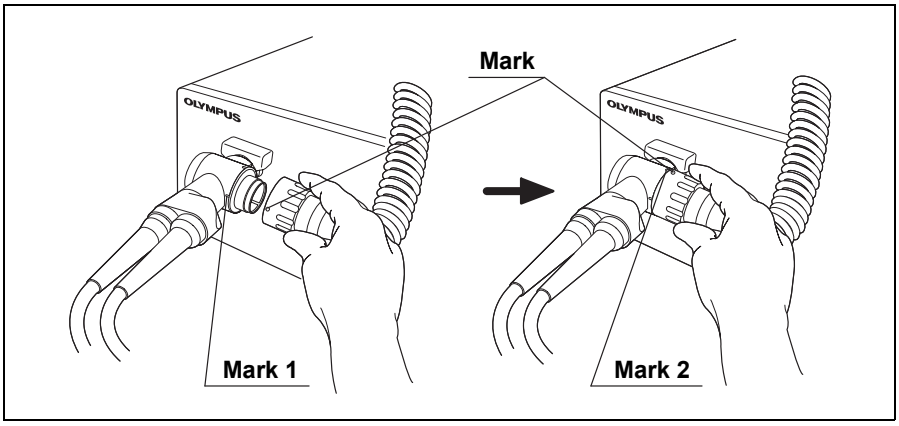


Figure 3.16

13. Prepare the record equipment of an ultrasonic picture if necessary, and connect it according to the manual.

3.6 Inspection of the endoscopic system

Inspection of the endoscopic image

WARNING

Do not stere directly at the distal end of the endoscope while examination light is output from it. Otherwise, eye damage may result.

1. Turn ON the power switch of the light source, video system center and video monitor as described in their respective instruction manuals.
2. While observing the palm of your hand, confirm that the examination light is output and that the endoscopic image is free from noise, blur, fog or other irregularities.
3. Angurate the endoscope and confirm that the endoscopic image is free from momentary disappearing or other irregularities.

NOTE

If the object cannot be seen clearly, wipe the objective lens using a clean, lint-free cloth moistened with 70% ethyl or isopropyl alcohol.

Inspection of the suction function

WARNING

- If the suction valve does not work smoothly, detach it and attach it again or replace it with a new suction valve. If it still does not work smoothly, the endoscope may be malfunctioning; stop using it and contact Olympus. If the endoscope is used while the suction valve is not working smoothly, the valve may be stuck which may make it impossible to stop the suction operation.
- Do not aspirate with a pressure of more than 670 hPa (0.68 kgf/cm^2, 9.7 psia). Using higher pressure may make it difficult to stop suction.

1. Immerse the distal end of the insertion tube in sterile water and depress the suction valve. Confirm that water is continuously aspirated into the suction bottle of the suction pump.
2. Release the suction valve. Confirm that suction stops and the valve returns to its original position.

3. Remove the distal end of the insertion tube from the water. Depress the suction valve and aspirate air for a few seconds to remove water from the instrument channel.

Inspection of the instrument channel

CAUTION

Keep your eyes away from the distal end when inserting EndoTherapy accessories. Extending the EndoTherapy accessory from the distal end could cause eye injury.

1. Insert the EndoTherapy accessory through the biopsy valve. Confirm that the EndoTherapy accessory extends smoothly from the distal end.
2. Confirm that the EndoTherapy accessory can be withdrawn smoothly from the biopsy valve.

Inspection of the water feed

1. Insert a syringe filled with sterile water into the biopsy valve and depress the plunger.
2. Confirm that water is emitted from the distal end.

NOTE

- The syringe must be inserted fully and held perpendicular to the valve for proper operation. Angled or incomplete insertion may result in fluid leakage from the biopsy valve.
- Do not depress the suction valve during feeding. If the suction valve is depressed during water feeding, water will be aspirated into the suction tube and not emitted from the endoscope's distal end.
- If fluid is not emitted from the endoscope's distal end, flush air through the channel.

Inspection of the water feeding function into the balloon

NOTE

If the balloon is over-inflated, sterile water will leak from the distal end in order to prevent balloon rupture or detachment. Therefore, it is desirable to use saline solution for avoiding patient coughs.

1. Connect the extension tube, three-way stopcock and syringe to the irrigation port as shown in Figure 3.17.
2. Fill the syringe with 10 to 15 cm^3 (10 to 15 ml) of sterile, de-aerated water, or saline and connect it to the three-way stopcock and depress the plunger.
3. Confirm that water is emitted from the distal end.

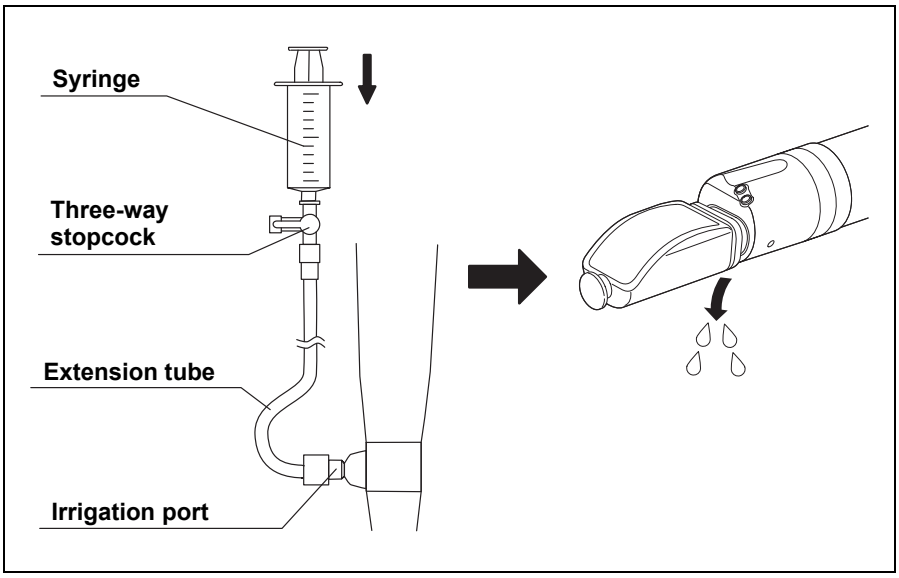


Figure 3.17

Inspection of the ultrasonic image

1. Inspect the compact endoscopic ultrasound center as described in its instruction manual.
2. Turn ON the compact endoscopic ultrasound center.
3. Press the “US/EXT” switch and make sure that the initial image is displayed on the video monitor (see Figure 3.18).

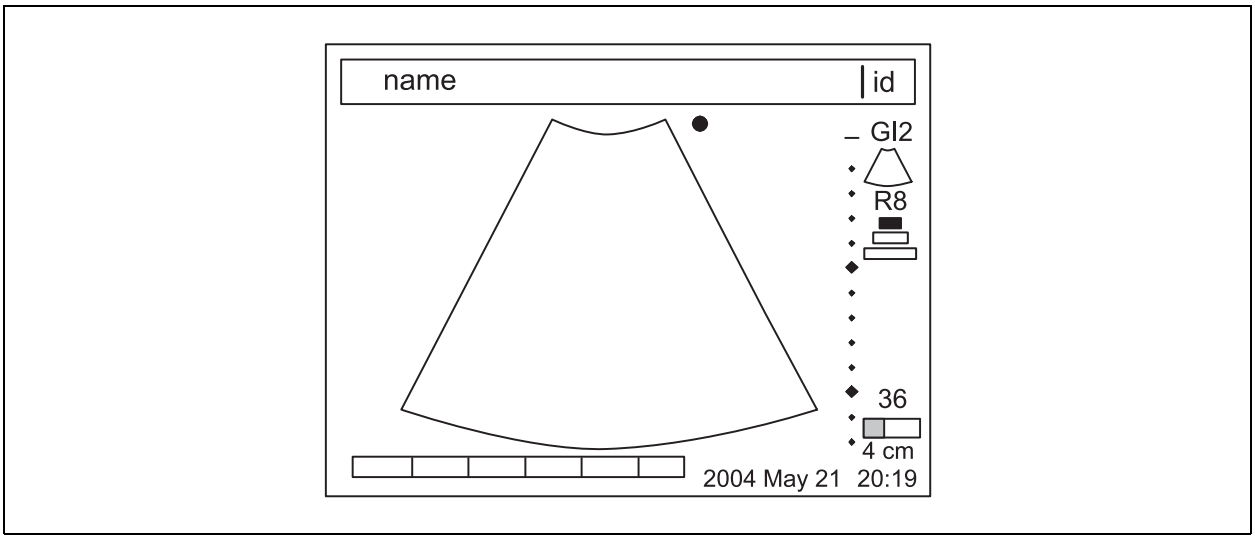


Figure 3.18

3.7 Preparation and inspection of the balloon

WARNING

- Balloons used with this instrument contain natural rubber latex which may cause allergic reactions in some individuals. Do not use the balloon on a latex-sensitive patient.
- The balloons are disposable and are intended for a single-use only. A new one must be used for each patient. Do not attempt to reuse or sterilize a balloon.
  This could pose an infection-control risk or cause equipment damage.
- Confirm that the balloon applicator has been properly reprocessed as described in Chapters 5, “Reprocessing: General Policy” through 7, “Cleaning, Disinfection and Sterilization Procedures”.
- If you find a peel pack that is open, damaged or soiled, do not use the balloon in that pack.

CAUTION

- The balloon can easily tear, so beware of sharp objects.
- Store the balloon in a cool environment with low humidity.
- After opening the laminate package, reseal it securely. If the laminate package remains open, the efficacy of the deoxidizer will be reduced.

Attaching the balloon

1. Prepare the balloon and the balloon applicator.
2. Inspect the balloon and confirm that it has no holes, swelling, color changes or any other irregularities. If an irregularity is detected, do not use the balloon; use a spare instead, inspecting it thoroughly before use.
3. Grab the tip of the balloon with the applicator. Fold the rear band back onto the applicator (see Figure 3.19).

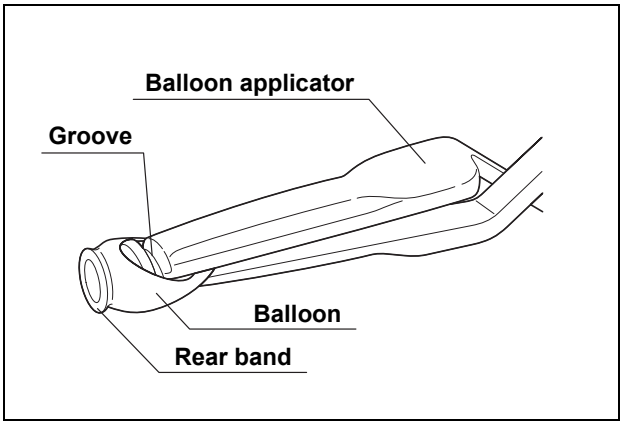


Figure 3.19

4. Position the rear band onto the groove of the applicator (see Figure 3.20).

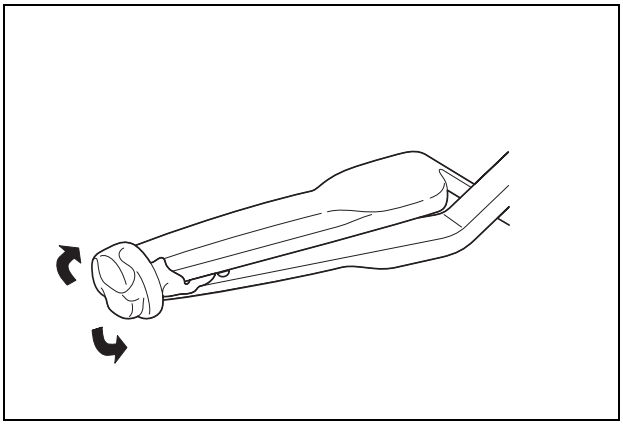


Figure 3.20

5. Open the applicator wide enough to fit the transducer of the endoscope into it (see Figure 3.21).

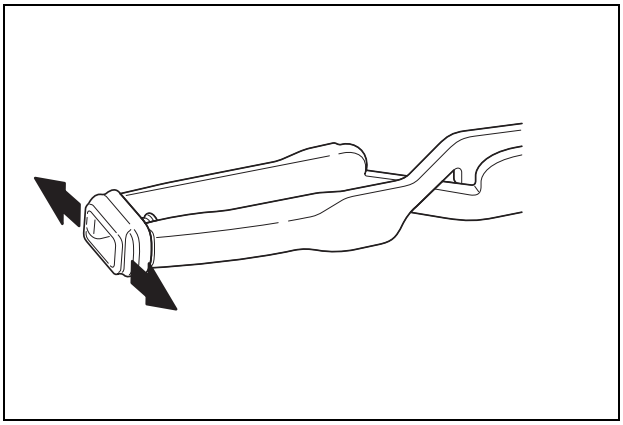


Figure 3.21

CAUTION

In step 6. to 8. below, do not apply excessive force to or bend the distal end of the endoscope. Instrument damage may occur.

6. Insert the transducer of the endoscope into the balloon (see Figure 3.22).

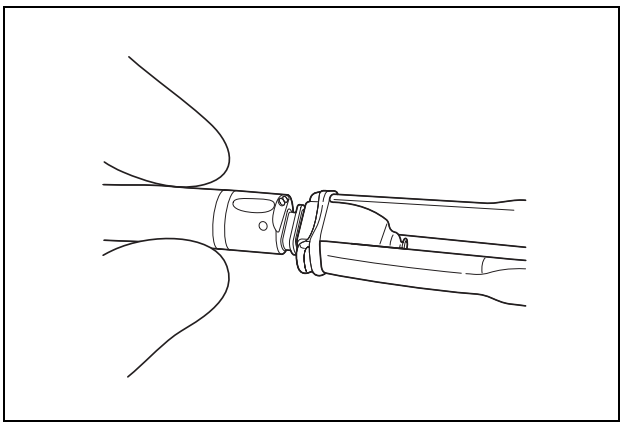


Figure 3.22

7. Put the rear band of the balloon into the rear balloon groove of the endoscope. Then, move the applicator DOWN, away from the distal end of the endoscope (see Figure 3.23).

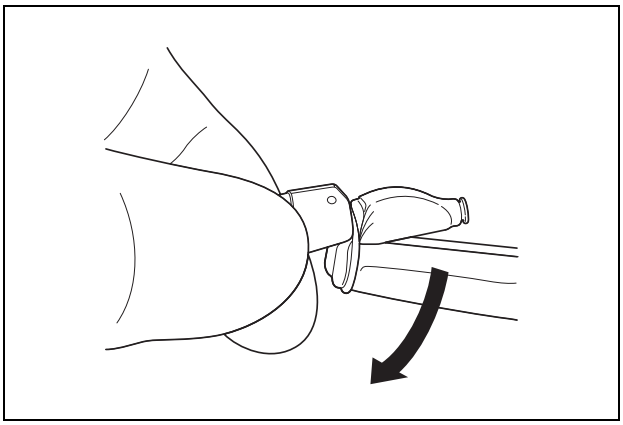


Figure 3.23

8. After performing the steps above, the balloon should be attached to the scope (see Figure 3.24).

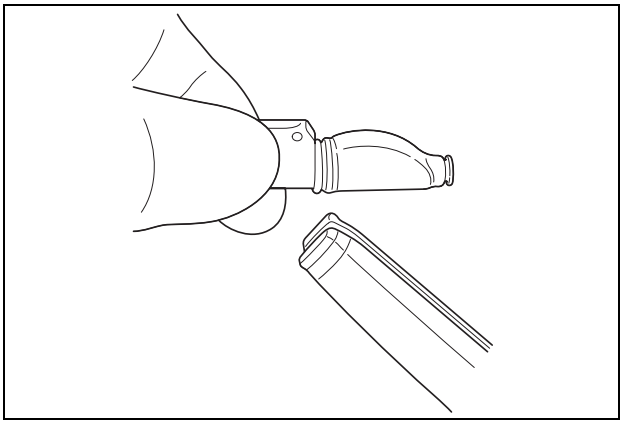


Figure 3.24

9. Fill the syringe with sterile de-aerated water or saline.

10. Connect the syringe to the three-way stopcock and depress the plunger to inflate the balloon. While inflating the balloon, point the distal end of the endoscope upward (see Figure 3.25).

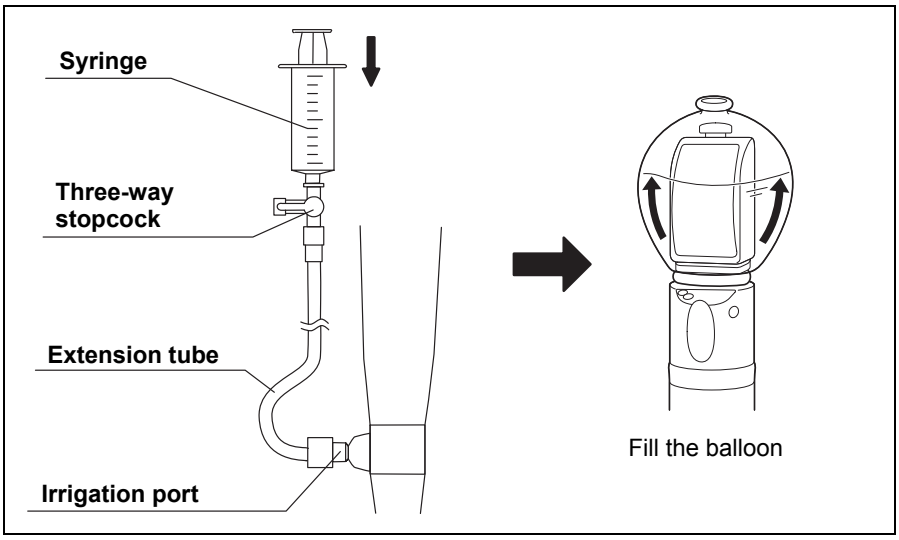


Figure 3.25

NOTE

In Step 10., the balloon's front band is not attached to the endoscope's balloon attachment groove. Therefore, water will be emitted from the front end of the balloon. Place the distal end of the endoscope in a beaker or any other container to prevent the floor from getting wet.

11. Gently grip the balloon with your fingers and squeeze out air bubbles from the front end of the balloon (see Figure 3.26).

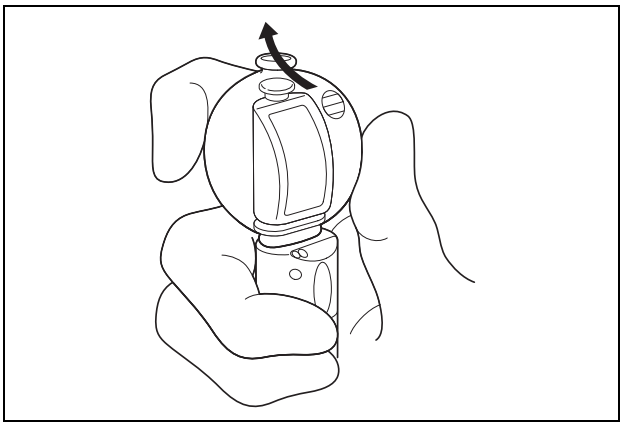


Figure 3.26

CAUTION

Do not apply excessive force to or bend the distal end of the endoscope. Instrument damage may occur.

12. Attach the front band of the balloon to the endoscope's balloon attachment groove.

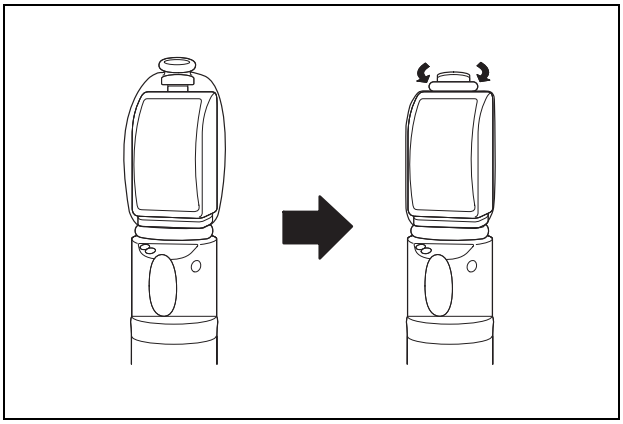


Figure 3.27

Inspection of the balloon and expelling air

1. Inflate the balloon to a diameter of about 10 mm by pushing the syringe's plunger. Confirm that there is no water leakage in the balloon.
2. Visually confirm that there are no air bubbles in the balloon.
3. If the balloon has no air bubbles and no water leakage has been detected, deflate the balloon by pulling the syringe's plunger. Turn the three-way stopcock to stop feeding water.
4. If the water leaks from the band of the balloon, press the band into the balloon groove (see Figure 3.23).
5. If the water leaks from the band of the balloon, press the band into the balloon groove (see Figure 3.25).

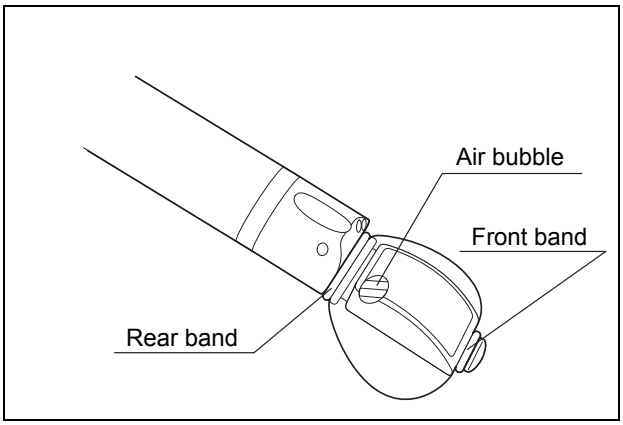


Figure 3.28

6. After confirming that there are no water leakage and no air bubbles in the balloon, deflate the balloon by pulling the syringe's plunger. Turn the three-way stopcock to stop feeding water.

WARNING

Never tie both ends of the balloon with sterile cotton thread. This may cause the balloon to rupture or come off the distal end of the endoscope when over-inflated. This can result in patient injury.

Chapter 4 Operation

The operator of this instrument must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique. This manual, therefore, does not explain or discuss clinical endoscopic procedures. It only describes basic operation and precautions related to the operation of this instrument.

WARNING

- Wear personal protective equipment to guard against dangerous chemicals and potentially infectious material. During operation, wear appropriate personal protective equipment, such as eye wear, face mask, moisture-resistant clothing and chemical-resistant gloves that fit property and are long enough so that your skin is not exposed.
- The temperature of the distal end of the endoscope may exceed 41°C (106°F) and reach 50°C (122°F) due to intense endoscopic illumination. Surface temperatures over 41°C (106°F) may cause mucosal burns. Always use the minimum level of illumination, minimum time and suitable distance necessary for adequate viewing. Whenever possible, avoid close stationary viewing and do not leave the distal end of the endoscope close to the mucous membrane for a long time.
- Whenever possible, do not leave the endoscope illuminated before and/or after an examination. Continued illumination will cause the distal end of the endoscope to become hot and could cause operator and/or patient burns.
- Turn the video system center ON to operate the light source's automatic brightness function. When the video system center is OFF, it cannot operate the light source's automatic brightness function, and the light intensity is set to the maximum level. In this case, the distal end of the endoscope can become hot and could cause operator and/or patient burns.
- Never insert or withdraw the endoscope under any of the following conditions. Otherwise, patient injury can result.
  - While the EndoTherapy accessory extends from the distal end of the endoscope.
  - While the bending section is locked in position.
  - Use of excessive force, or forcible insertion or withdrawal.

- If any of the following phenomena occur during an examination, immediately stop the examination and withdraw the endoscope from the patient as described in section 10.2, “Withdrawal of the endoscope with an abnormality”.
  - If any abnormality is suspected with the functionality of the endoscope.
  - If the endoscopic image on the video monitor disappears or freezes unexpectedly.
  - If the angulation control mechanism is not functioning properly.

  Continued use of the endoscope under these conditions could result in patient injury.
- If an abnormal endoscopic image/function occurs and returns to its normal condition by itself, the endoscope has malfunctioned. In this case, stop using the endoscope because the abnormality can occur again and may not return to its normal condition. Therefore, stop the examination immediately and slowly withdraw the endoscope while viewing the endoscopic image. Otherwise, patient injury can result.
- Always lubricate the balloon before insertion. Otherwise, the balloon could rupture or come off. This could result in patient injury.
- Never force the insertion section if resistance is encountered. Patient injury, perforation and/or equipment damage may occur.
- When using this instrument, never block the trachea with the balloon. This could result in suffocation.
- Deflate the balloon before withdrawing the endoscope from the patient. Withdrawing the endoscope while the balloon is inflated could result in patient injury.

4.1 Insertion

Holding and manipulating the endoscope

The control section of the endoscope is designed to be held in the left hand. The suction valve can be operated using the left index finger. The UP/DOWN angulation control lever can be operated using the left thumb. The right hand is free to manipulate the insertion tube (see Figure 4.1).

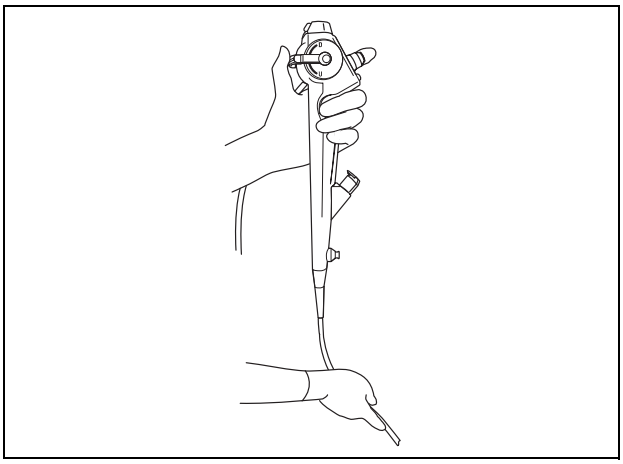


Figure 4.1

Insertion of the endoscope

CAUTION

- Do not apply olive oil or products containing petroleum-based lubricants (e.g. Vaseline). These products may cause stretching and deterioration of the bending section's covering.
- To prevent the patient from accidentally biting the insertion tube, it is strongly recommended that a mouthpiece be placed in the patient's mouth before inserting the endoscope.
- Do not allow the insertion tube to be bent within a distance of 10 cm or less from the junction of the boot. Insertion tube damage can occur (see Figure 4.2).

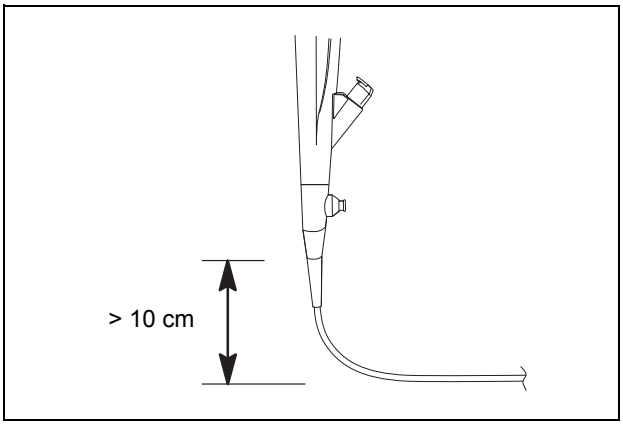


Figure 4.2

1. Apply a medical-grade, water-soluble lubricant to the insertion tube and balloon.
2. Place the mouthpiece between the patient's teeth or gums, with the outer flange on the outside of the patient's mouth.
3. Insert the distal end of the endoscope through the opening of the mouthpiece, then from the mouth to the pharynx, while viewing the endoscope image.

Angulation of the distal end

WARNING

If the angulation control mechanism or any other part of the system is not functioning properly, stop the procedure immediately; do not operate the angulation control lever unless absolutely necessary. Then carefully withdraw the endoscope while observing the endoscopic image. If the endoscope cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it; leave it inside the patient and immediately contact Olympus. Forcibly withdrawing the endoscope may cause patient injury.

Operate the angulation control lever as necessary to guide the distal end for insertion and observation.

Feeding fluids suction

❍ Feeding fluids

NOTE

Do not depress the suction valve while feeding fluids. Otherwise, the fluids will be aspirated into the suction pump.

Securely insert a syringe into the slit of the biopsy valve and press the plunger.

❍ Suction

WARNING

Avoid aspiration solid matter or thick fluids; channel or valve clogging can occur. If the suction valve clogs and suction cannot be turned OFF, disconnect the suction tube from the suction valve. Stop the procedure and withdraw the endoscope from the patient while viewing the endoscopic image.

CAUTION

During the procedure, make sure that the suction bottle does not fill completely or overflow. Aspirating fluids into a full bottle can damage the suction pump.

Depress the suction valve to aspirate excess fluids or other debris while observing the endoscopic image (see Figure 4.3).

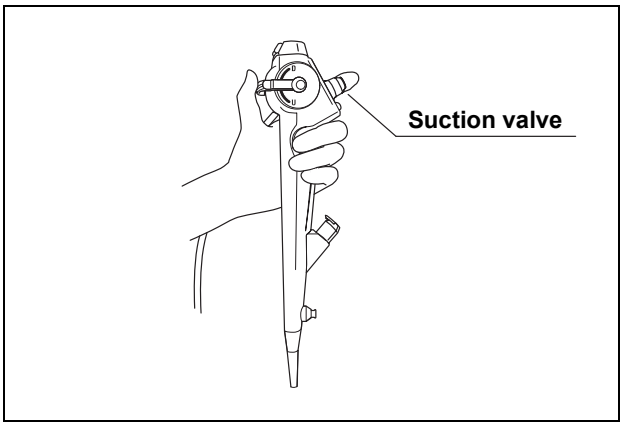


Figure 4.3

Observation of the endoscopic image

Refer to the light source's instruction manual for instructions on how to adjust the brightness.

NOTE

- For this endoscope, the brightness setting on the video system center is too high. Set the iris mode selection switch on the video system center to peak iris mode. However, when the image turns dark by using EndoTherapy accessories, set the iris mode selection switch to the average iris mode.
- For adjusting the white balance of this endoscope, set the iris mode selection switch on the video system center to peak iris mode. Otherwise, it may not be possible to correctly adjust the white balance.

4.2 Observation of the ultrasonic image

CAUTION

Do not inflate the balloon to a diameter of more than 2 cm.

NOTE

If the balloon is over-inflated, sterile water will leak from the balloon attachment groove in order to prevent balloon rupture or detachment from the endoscope.

1. Position the distal end of the endoscope beyond the target site and press the “FREEZE” switch on the endoscopic ultrasound center to change the ultrasonic image to REAL-TIME mode.
2. Turn the three-way stopcock and inflate the balloon to the desired diameter by pushing the syringe’s plunger. When inflation is complete, turn again the three-way stopcock to stop water feeding.

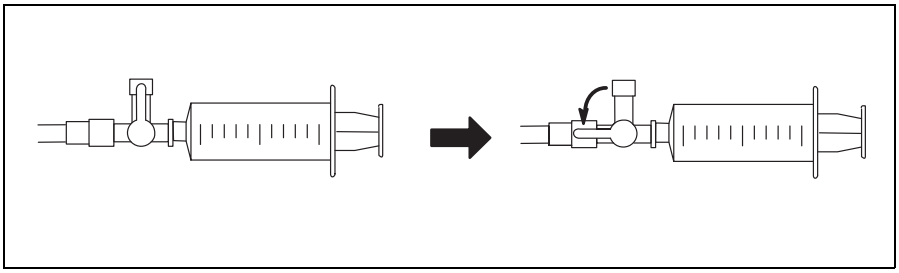


Figure 4.4

3. When the ultrasonic image of the target appears, adjust the endoscopic ultrasound center as described in its instruction manual to obtain a suitable image.
4. Use the endoscope’s angulation mechanism to bring the balloon into full contact with the tracheal or bronchial wall. Move the distal end of the endoscope to the target site.

CAUTION

Deflate the balloon and keep the endoscopic ultrasound center in the FREEZE mode, except during ultrasonic observation.

4.3 Using EndoTherapy accessories

For more information on combining the endoscope with particular EndoTherapy accessories, refer to the “System chart” in the Appendix and the instruction manuals of the accessories. Refer to the instruction manuals of the accessories for instructions on how to operate the accessories.

WARNING

- Never use high frequency EndoTherapy accessories, because the distal end of this instrument is not isolated. Using high frequency accessories places the patient at risk of electric shock.
- When using EndoTherapy accessories, keep the distance between the objective lens of the endoscope and the mucous membrane greater than the endoscope’s minimum visible distance so that the EndoTherapy accessory remains visible in the endoscopic image. If the objective lens of the endoscope is placed closer than its own minimum visible distance, the position of the accessory cannot be seen in the endoscopic image, which could cause serious patient injury and/or equipment damage. The minimum visible distance depends on the type of endoscope being used. Refer to Section 2.3, “Specifications” on page 16.
- This endoscope does not correspond to laser cauterization, If laser cauterization is performed, abnormalities in an endoscopic image may occur, which consequently may damage the inside of the patient body.
- Do not use the channel cleaning brush for cytologic tissue sampling or other diagnostic or therapeutic purposes. Patient injury, cross-contamination and/or equipment damage may occur.
- Ultrasound guided needle aspiration should only be performed when the needle is visible in the ultrasonic image.
- If the ultrasonic image disappears while using the needle, stop the procedure immediately and withdraw the needle from the tissue.
- Do not insert or withdraw EndoTherapy accessories while the endoscope is angulated.
  Inserting or withdrawing an EndoTherapy accessory with force may damage the EndoTherapy accessory or endoscope and/or cause patient injury.

- If an EndoTherapy accessory cannot be withdrawn from the endoscope, close the tip of the EndoTherapy accessory or retract the tip of the EndoTherapy accessory into its sheath and slowly withdraw the endoscope while observing the endoscopic image.

Insertion of EndoTherapy accessories into the endoscope

WARNING

- Do not insert EndoTherapy accessories forcibly or abruptly. Otherwise, the EndoTherapy accessory may extend from the distal end of the endoscope abruptly, which could cause patient injury, bleeding, and/or perforation.
- The force required to insert an EndoTherapy accessory is reduced if the cap of the biopsy valve (MD-495) is detached from the main body. However, a detached cap can reduce the efficacy of the endoscope's suction system and may cause patient debris to leak or spray from the endoscope. Whenever EndoTherapy accessories are not being used, attach the biopsy valve's cap to the main body.

1. Select the EndoTherapy accessories compatible with the instrument from the "System chart" in the Appendix. Also refer to the instruction manuals of the EndoTherapy accessories.
2. Turn the UP/DOWN angulation control lever to the neutral position to straighten the endoscope.
3. Confirm that the tip of the EndoTherapy accessory is closed or retracted into its sheath and insert the EndoTherapy accessory slowly and straight into the slit of the biopsy valve.

CAUTION

- Do not open the tip of the EndoTherapy accessory or extend the tip of the EndoTherapy accessory from its sheath while inserting the EndoTherapy accessory into the instrument channel. The instrument channel and/or the EndoTherapy accessory may become damaged.
- Hold the EndoTherapy accessory close to the biopsy valve and insert it straight into the biopsy valve using slow, short strokes. Otherwise, the EndoTherapy accessory could bend or break.

4. Hold the EndoTherapy accessory approximately 4 cm from the biopsy valve and advance it slowly and straight into the valve using slow, short strokes while observing the endoscopic image.

Operation of EndoTherapy accessories

Operate the EndoTherapy accessory according to the directions given in its instruction manual.

Withdrawal of EndoTherapy accessories

WARNING

- Do not withdraw the EndoTherapy accessory if the tip is open or extended from its sheath; patient injury and/or instrument damage may occur.
- If the EndoTherapy accessory cannot be withdrawn from the endoscope, carefully withdraw both the endoscope and the EndoTherapy accessory together under endoscopic observation. Take care not to cause tissue trauma.

Withdraw the EndoTherapy accessory slowly while the tip of the EndoTherapy accessory is closed and/or retracted into its sheath.

Bronchoalveolar lavage

❍ Using the BAL (bronchoalveolar lavage) kit

1. Disconnect the suction pump tube from the suction connector of the suction valve. Connect the suction pump tube to the suction connector of a commercially available BAL kit.
   Connect the BAL kit's suction line to the suction connector of the suction valve (see Figure 4.5).

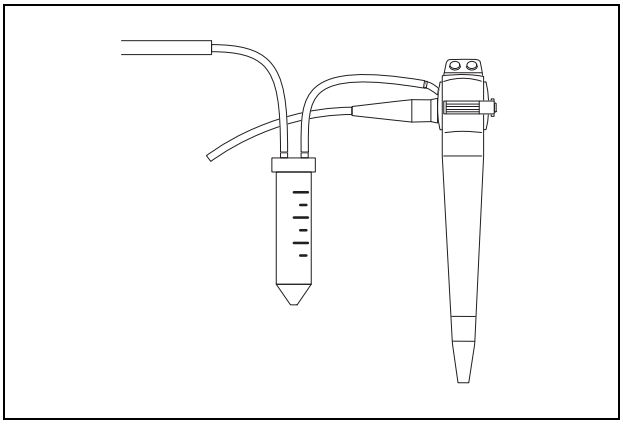


Figure 4.5

2. Securely insert a syringe filled with lavage fluid (e.g. saline) into the slit of the biopsy valve and press the plunger to feed lavage fluid.
3. Depress the suction valve to aspirate lavage fluid.

Using a syringe

1. When using the biopsy valve (MD-495), remove it first, then insert the syringe directly into the instrument channel port.
   When using the single-use biopsy valve (MAJ-210), securely insert a syringe into its slit.
2. Press the plunger to feed lavage fluid (see Figure 4.6 a).
3. With the syringe attached, slowly withdraw the plunger to aspirate lavage fluid (see Figure 4.6 b).

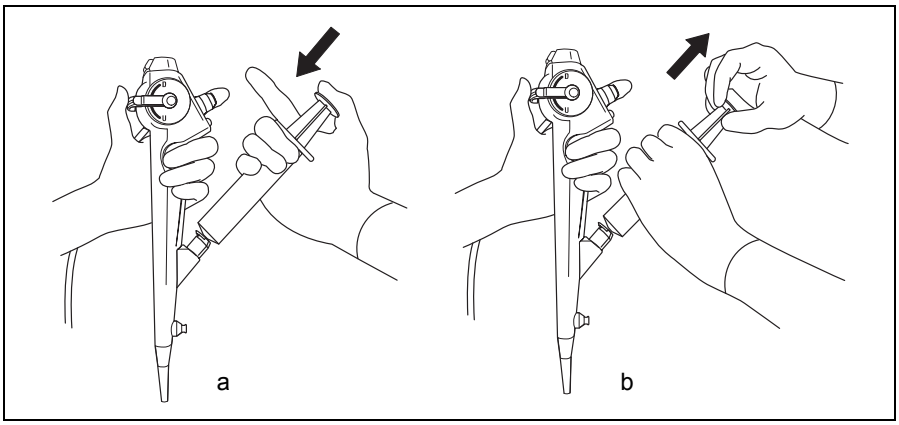


Figure 4.6

4.4 Withdrawal of the endoscope

WARNING

- If blood unexpected adheres to the surface of the insertion tube of the withdrawed endoscope, check the conditions of the patient carefully.
- Observe the endoscopic image or the ultrasonic image on the video monitor and confirm that the balloon deflates properly. Otherwise, patient injury may occur.
- If the balloon does not deflate even when the extension tube is removed from the endoscope, insert the channel cleaning wire (BW-16C) into the irrigation port to remove debris. The balloon will be automatically deflated.
- If the endoscope cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it; leave it inside the patient and immediately contact Olympus. Forcibly withdrawing the endoscope may cause patient injury.

1. Open the three-way stopcock.
2. Deflate the balloon by pulling the syringe's plunger.
3. FREEZE the ultrasonic image.
4. Carefully withdraw the endoscope while observing the endoscopic image.
5. Remove the mouthpiece from the patient's mouth.
6. Detach and discard the balloon in an appropriate manner.

4.5 Transportation of the endoscope

Transporting within the hospital

When carrying the endoscope by hand, hold the endoscope connector and ultrasonic connector together with the control section in one hand and hold the distal end of the insertion tube securely, but gently without squeezing, in the other hand (see Figure 4.7).

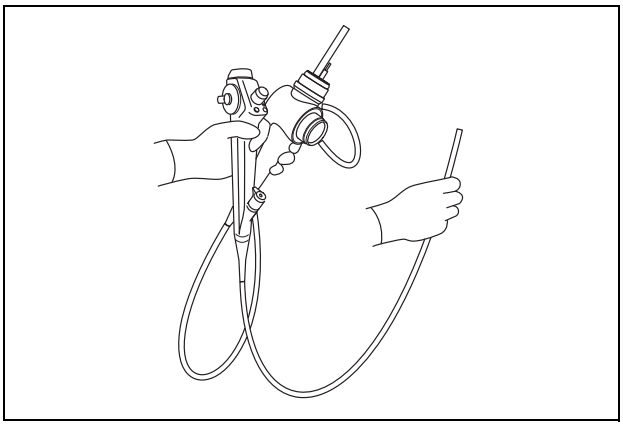


Figure 4.7

Transporting outside the hospital

Transport the endoscope in the carrying case.

WARNING

Always clean, disinfect or sterilize the endoscope after removing it from the carrying case.

CAUTION

- The carrying case cannot be cleaned or disinfected. Clean and disinfect or sterilize the endoscope before placing it in the carrying case. Disinfect or sterilize the endoscope again before use.
- Do not attach the water-resistant caps when transporting the endoscope, to avoid damage to the endoscope caused by changes in air pressure.

Chapter 5 Reprocessing: General Policy

5.1 Instructions

- Chapters 5, “Reprocessing: General Policy” through 8, “Cleaning and Disinfection Equipment” describe recommended procedures and equipment for cleaning and disinfecting or sterilizing this instrument.
- Before reprocessing, thoroughly review the manuals of reprocessing chemicals and all equipment which will be used, and reprocess the equipment as instructed.

5.2 Notes for Cleaning, Disinfection and Sterilization

- The medical literature reports incidents of patient cross contamination resulting from improper cleaning, disinfection or sterilization. It is strongly recommended that reprocessing personnel have a thorough understanding of and follow all national and local hospital guidelines and policies.
- A specific individual or individuals in the endoscopy unit should be responsible for reprocessing endoscopic equipment. It is highly desirable that a trained backup be available should the primary reprocessing individual(s) be absent.
- All individuals responsible for reprocessing should thoroughly understand:
  - occupational health and safety regulations
  - all national and local hospital guidelines and policies
  - the instructions in this manual
  - the mechanical aspects of endoscopic equipment
  - pertinent germicide labeling

5.3 Precautions

WARNING

- ALL channels of the endoscope, including balloon channels where fitted, MUST be cleaned and high-level disinfected or sterilized during EVERY reprocessing cycle, even if the channels were not used during the previous patient procedure. Otherwise, insufficient cleaning and disinfection or sterilization of the endoscope may pose an infection control risk to the patient and/or operators performing the next procedure with the endoscope.
- Failure to properly clean and high-level disinfect or sterilize endoscopic equipment after each examination can compromise patient safety. To minimize the risk of transmitting diseases from one patient to another, after each examination the endoscope must undergo thorough manual cleaning followed by high-level disinfection or sterilization.
- Olympus confirms validation of the endoscope reprocessors recommended by Olympus only. If using endoscope reprocessor that are not recommended by Olympus, the endoscope reprocessor manufacturers are responsible for validation of the endoscope reprocessor with the endoscope models listed in its intended use statement. If using an endoscope reprocessor, confirm that it is capable of reprocessing endoscope including all channels. If there are channels and/or other parts which cannot be cleaned and high-level disinfected by the endoscope reprocessor, have to undergo manual cleaning and high-level disinfection or sterilization as described in Chapter 7, “Cleaning, Disinfection and Sterilization Procedures” after using the endoscope reprocessor. Otherwise, insufficient cleaning and disinfection or sterilization of the endoscope may pose an infection control risk to the patient and/or operators performing the next procedure with the endoscope. If you are uncertain as to the ability of your endoscope reprocessor to clean and high-level disinfect endoscope including all channels, contact the endoscope reprocessor supplier for specific instructions and/or connectors.

- If the endoscope is not cleaned meticulously, effective disinfection or sterilization may not be possible. Clean the endoscope and accessories thoroughly before disinfection or sterilization to remove microorganisms or organic material that could reduce the efficacy of disinfection or sterilization.
- Patient debris and reprocessing chemicals are hazardous. Wear personal protective equipment to guard against dangerous chemicals and potentially infectious material. During cleaning and disinfection or sterilization, wear appropriate personal protective equipment, such as eye wear, face mask, moisture-resistant clothing and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed. Always remove contaminated personal protective equipment before leaving the reprocessing area.
- Thoroughly rinse off the disinfectant solution. Rinse the external surface of the endoscope, channels and cleaning equipment thoroughly with clean water to remove any disinfectant solution residue.
- The disinfection/sterilization room must be adequately ventilated. Adequate ventilation protects against the buildup of toxic chemical fumes.
- Store alcohol in an air-tight container. Alcohol stored in an open container is a fire hazard and will lose its efficacy due to evaporation.
- With the cleaning, disinfection and sterilization methods stated in this instruction manual, prions, which are considered to be the pathogenic substance of the Creutzfeldt-Jakob disease (CJD) cannot be destroyed or inactivated. When using this instrument on a patient with CJD or variant Creutzfeldt-Jakob disease (vCJD), be sure to use this product for such patient only and/or immediately dispose of this product after use in an appropriate manner. For methods to handle CJD, please follow the respective guidelines in your country.

- This instrument is not durable, or does not have sufficient durability against the respective methods stated in the guidelines of each country for destroying or inactivating prions. For information on the durability against each method, please contact Olympus. If cleaning, disinfection and sterilization methods not stated in this instruction manual are performed, Olympus cannot guarantee the effectiveness, safety and durability of this instrument. Make sure to confirm that there is no abnormality before use, and use under responsibility of a physician. Do not use if any abnormality is found.

CAUTION

- When aerating or irrigating the endoscope channels, the air or water pressure must not exceed 0.2 MPa (2 kgf/cm^2, 29 psig).
- Before immersing the endoscope in cleaning or disinfectant solution, confirm that the water-resistant caps are attached electrical connector and ultrasonic connector.

Chapter 6 Compatible Reprocessing Methods and Chemical Agents

6.1 Compatibility summary

Olympus endoscopic equipment is compatible with several methods of reprocessing. Certain components and accessories, however, are not compatible with some methods, which can cause equipment damage. For appropriate reprocessing methods, refer to Table 6.1 below, the recommendations of your infection control committee and all national and local hospital guidelines and policies.

	Steam sterilization (autoclave)	ETO gas sterilization	2 – 3.5% glutaraldehyde	70% ethyl or isopropyl alcohol	Detergent solution	Ultrasonic cleaning
Endoscope	**∗1**					
Water-resistant cap (MAJ-1057, MH-553) **Cap chain (MAJ-1193)**	**∗1**					
Balloon applicator (MAJ-1352)						
Channel cleaning brush (BW-15B) **Channel cleaning wire (BW-16C)** **Channel-opening cleaning brush (MH-507)**						
Suction valve (MAJ-207) **Biopsy valve (MD-495)** **Suction cleaning adapter (MAJ-222)** **Mouthpiece (MA-651)**						

applicable **not applicable**

Table 6.1

∗1 The endoscope is compatible with ultrasonic cleaning by endoscope reprocessor (OER) only.

NOTE

EndoTherapy accessories which are marked by the words “AUTOCLAVE” or “AUTOCLAVABLE”, or accessories with a green model reference label are compatible with autoclaving.

6.2 Water (for reprocessing)

Water is used for leakage testing and manual cleaning of the endoscope and accessories. For these purposes, use either fresh, potable tap water or water that has been processed (e.g., filtered, deionized or purified) to improve its chemical and/or microbiological quality. Consult with your hospital's infection control committee.

When rinsing the endoscope and accessories following high-level disinfection, use the water referred to in Section 6.5, "Rinsing water".

6.3 Detergent solution

Use a medical-grade, low-foaming detergent (neutral pH detergent or enzymatic detergent) and follow the manufacture's dilution and temperature recommendations. Contact Olympus for the names of specific brands that have been tasted for compatibility with the endoscope. Do not reuse detergent solutions.

WARNING

Excessive detergent foaming can prevent fluid from adequately contacting internal lumens (e.g. channels).

6.4 Disinfectant solution

In the U.S., agents used to achieve high-level disinfection are defined as liquid chemical germicides registered with the U.S. Food and Drug Administration as "sterilant/disinfectants" which are used according to the time, temperature and dilution recommended by the disinfectant manufacturer for achieving high-level disinfection. These conditions usually coincide with those recommended by the disinfectant manufacturer for 100% kill of mycobacterium tuberculosis.

In general, 2.0 – 3.5% glutaraldehyde solutions, when used according to the manufacturer's instructions for achieving high-level disinfection, are compatible with Olympus endoscopes. Contact Olympus for the names of specific brands that have been tested for compatibility with this endoscope.

If disinfectant solution is reused, routinely check its efficacy with a test strip recommended by the manufacturer. Do not use solutions beyond their expiration date.

WARNING

Alcohol is not a sterilant or high-level disinfectant.

6.5 Rinsing water

Once removed from disinfectant solution, the instrument must be thoroughly rinsed with sterile water to remove any disinfectant residue. If sterile water is not available, clean potable tap water or water which has been processed (e.g. filtered) to improve its microbiological quality may be used.

When non-sterile water is used after disinfection, wipe the endoscope and flush the channels with 70% ethyl or isopropyl alcohol, then air-dry all internal channels to inhibit the growth of residual bacteria. Do not reuse rinsing water.

6.6 ETO gas sterilization

This instrument and other accessories listed as compatible with ethylene oxide (ETO) gas sterilization in Table 6.1 can be sterilized by ETO gas and aerated within the parameters given in Tables 6.2 and 6.3. When performing ETO gas sterilization, follow the hospital's protocol and the sterilization equipment manufacturer's instructions.

WARNING

- Before sterilization, the instrument must be thoroughly cleaned and dried. Residual moisture inhibits sterilization.
- The results of sterilization depend on various factors such as how the sterilized instrument was packed or the positioning, method of placing and loading of the instrument in the sterilization device. Please verify the sterilization effects by using biological or chemical indicators. Also follow the guidelines for sterilization issued by medical administrative authorities, public organizations or the infection management sections at each medical facility, as well as the instruction manual of the sterilization device.
- All instruments must be properly aerated following ETO gas sterilization to remove toxic ethylene oxide residuals.

CAUTION

- Exceeding the recommended parameters may cause equipment damage.

- Always remove the water resistant cap before ETO gas sterilization. The water-resistant cap may be damaged if they are subjected to ETO gas sterilization. If the water-resistant cap remains attached during ETO gas sterilization, the air inside the endoscope will expand and could rupture the covering of the bending section and/or damage the angulation mechanism.

❍ Parameters for 100% ethylene oxide gas sterilization cycles

Process phase	Parameter	value
Sterilization	**Temperature**	55°C (130°F)
	Vacuum (Absolute pressure)	0.05 – 0.07 MPa (7.25 – 10.15 psia)
	Relative humidity	50 – 80%
	Ethylene oxide gas concentration	0.735 – 0.740 mg/cm^3 (735 – 740 mg/L)
	Exposure time	60 minutes
Aeration	**Minimum aeration parameters**	12 hours in an aeration chamber at 50 – 57°C (122 – 135°F) or 7 days at room temperature

Table 6.2

❍ Parameters for 20% ethylene oxide gas/80% CO_2 gas sterilization cycles, for countries other than the USA

Process phase	Parameter	value
Sterilization	**Temperature**	57°C (135°F)
	Relative Pressure	0.1 – 0.17 MPa
	Relative humidity	55%
	Ethylene oxide gas concentration	0.6 – 0.7 mg/cm^3 (600 – 700 mg/L)
	Exposure time	105 minutes
Aeration	**Minimum aeration parameters**	12 hours in an aeration chamber at 50 – 57°C (122 – 135°F) or 7 days at room temperature

Table 6.3

6.7 Steam sterilization (autoclaving) of accessories

Steam sterilize (autoclave) within the parameters given in Table 6.4 below. When steam sterilizing, follow the hospital's protocol and the sterilization equipment manufacturer's instructions. Prior to steam sterilization (autoclaving) of accessories, meticulous manual cleaning followed by at least five minutes of ultrasonic cleaning at 38 – 47 kHz is required.

WARNING

- The results of sterilization depend on various factors such as how the sterilized instrument was packed or the positioning, method of placing and loading of the instrument in the sterilization device. Please verify the sterilization effects by using biological or chemical indicators. Also follow the guidelines for sterilization issued by medical administrative authorities, public organizations or the infection management sections at each medical facility, as well as the instruction manual of the sterilization device.
- Exceeding the recommended parameters may cause equipment damage.

CAUTION

- Do not steam sterilize the endoscope. Steam sterilization (autoclaving) will severely damage the endoscope.
- Effective sterilization will not be possible if items are packed tightly together in the autoclave; always pack items loosely.
- Inspect the instrument package for openings, tears and other damage. If an instrument package is opened or damaged, seal the components in a new package and sterilize again.
- Allow the packages to dry within the autoclave, using the autoclave's drying cycle (if available) or by opening the door of the autoclave and allowing the packages to air-dry. Handling a wet package can compromise its sterility.

NOTE

- EndoTherapy accessories and other items which are marked by the words "AUTOCLAVE" or "AUTOCLAVABLE", a green band or yellow-green marking are compatible with autoclaving.

- Some items with no markings are compatible with autoclaving. To determine the compatibility of such equipment with steam sterilization, refer to the item's instruction manual.

Process	Parameters	
Prevacuum	**Temperature**	132 – 134°C (270 – 274°F)
	Exposure time	5 minutes

Table 6.4 Steam sterilization (autoclaving) exposure parameters

Chapter 7 Cleaning, Disinfection and Sterilization Procedures

WARNING

ALL channels of the endoscope, including balloon channels where fitted, MUST be cleaned and high-level disinfected or sterilized during EVERY reprocessing cycle, even if the channels were not used during the previous patient procedure. Otherwise, insufficient cleaning and disinfection or sterilization of the endoscope may pose an infection control risk to the patient and/or operators performing the next procedure with the endoscope.

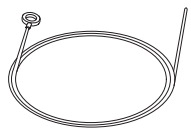
7.1 Required reprocessing equipment

Preparation of the equipment

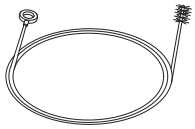
Prior to cleaning, disinfection or sterilization, prepare the equipment shown in Figure 7.1.

CAUTION

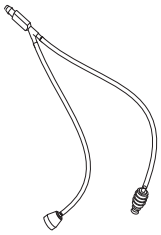
- Use basins which are at least 40 cm by 40 cm (16” by 16”) in size and deep enough to allow the endoscope to be completely immersed.
- Do not coil the endoscope’s insertion tube or universal cord or ultrasonic cable with a diameter of less than 12 cm. The endoscope can be damaged if coiled too tightly.



Channel cleaning wire (BW-16C)

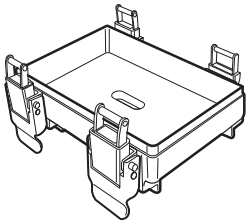


Channel cleaning brush (BW-15B)

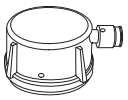


Suction cleaning adapter (MAJ-222)

Channel-opening cleaning brush (MH-507)

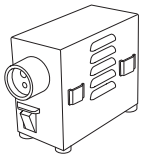


Water-resistant cap (MAJ-1057)

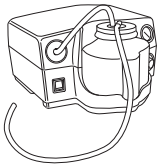


Water-resistant cap (MH-553)

Leakage tester (MB-155)



Maintenance unit (MU-1)



Suction pump (KV-4, KV-5, SSU-2)

• Detergent solution	• Disinfectant solution	• Personal protective equipment
• 500 cm^3 (500 ml) containers	• Large non-metallic basin with a tight fitting lid for detergent and disinfectant solution	• Clean, lint-free cloth
• Clean water (see Section 6.2)	• Large basin for rinsing and leakage testing	• Sterile, lint-free cloth
• Sterile water	• 30 cm^3 (30 ml) syringe	• Sterile, cotton swabs
• 70% ethyl or isopropyl alcohol	• Soft brush	• Small, containers

Figure 7.1

Reprocessing equipment parts and functions

For inspection of other equipment than that mentioned below, refer to the instruction manual for the equipment being used.

❍ Suction cleaning adapter (MAJ-222)

When reprocessing, the suction cleaning adapter is used to aspirate fluids from the distal end of the endoscope through the channel (see Figure 7.2).

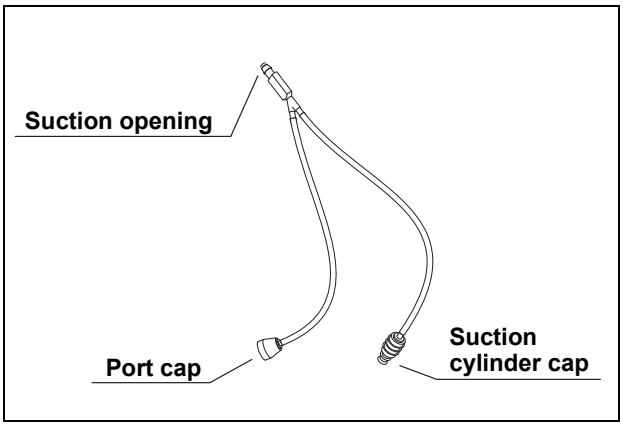


Figure 7.2

❍ Water-resistant cap (MAJ-1057)

This water-resistant cap is attached to the ultrasonic connector on the endoscope to protect the connector from water penetration during reprocessing. (see Figure 7.3).

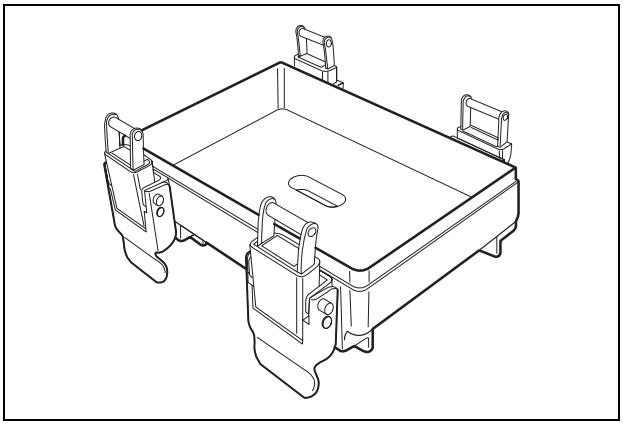


Figure 7.3

❍ Channel cleaning brush (BW-15B)

The channel cleaning brush is used to brush the inside of the instrument channel and the suction channel (see Figure 7.4).

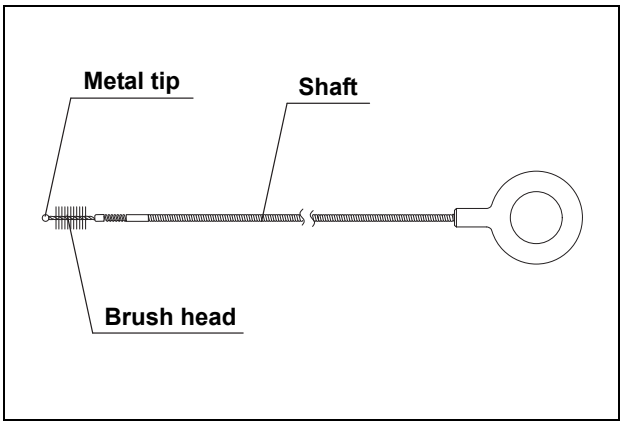


Figure 7.4

❍ Channel-opening cleaning brush (MH-507)

The channel-opening cleaning brush is used to brush the external surface of the distal end of the endoscope, the suction cylinder and the instrument channel opening (see Figure 7.5).

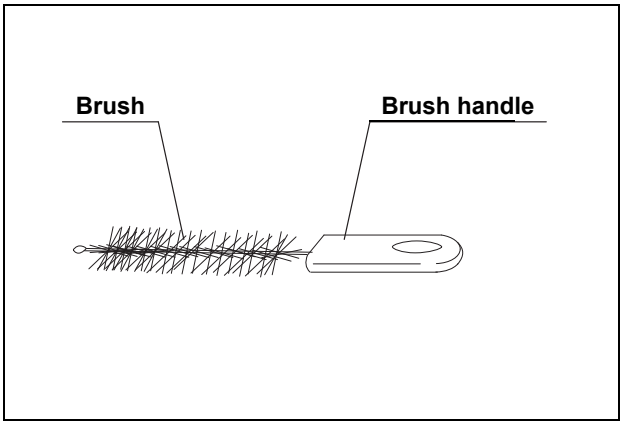


Figure 7.5

❍ Channel cleaning wire (BW-16C)

The channel cleaning wire is used to clean the balloon channel (see Figure 7.6).

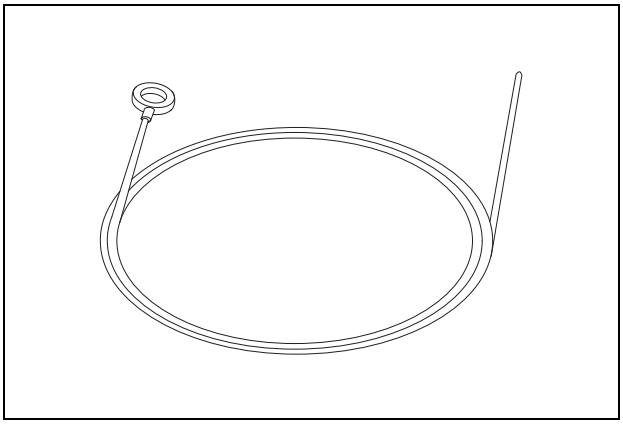


Figure 7.6

❍ Water-resistant cap (MH-553)

This water-resistant cap is attached to the electrical connector on the endoscope to protect the connector from water penetration during reprocessing. For leakage testing, the venting connector on the water-resistant cap must be connected to the leakage tester (MB-155) (see Figure 7.7).

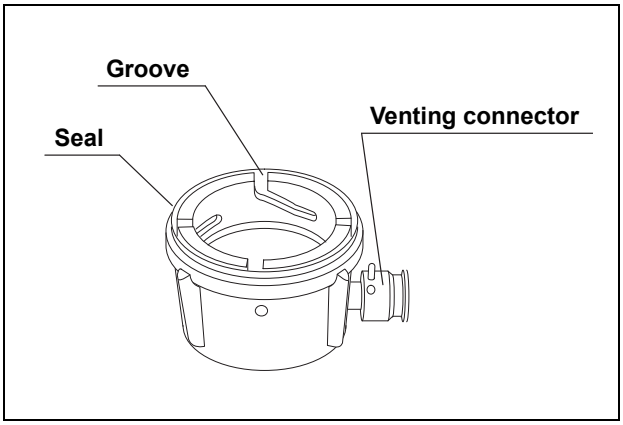


Figure 7.7

Inspection of equipment

For inspection of other equipment than that mentioned below, refer to the instruction manual for the equipment being used.

CAUTION

The cleaning brushes are consumable items. Should the slightest irregularity be suspected, use a spare instead. Using a defective brush may cause equipment damage.

❍ Inspection of the water-resistant caps

1. Confirm that the inside of the water-resistant caps are dry and free from debris (see Figures 7.3 and 7.7).
2. Confirm that the seal inside the water-resistant caps are free from scratches, flaws and debris.
3. Confirm that the latches on the MAJ-1057 are not damaged.

❍ Inspection of the suction cleaning adapter

Check for cracks, scratches, flaws, debris and other damage (see Figure 7.2).

❍ Inspection of the channel cleaning brush

1. Confirm that the brush section and the metal tip of the distal end are securely in place. Check for loose or missing bristles (see Figure 7.4).
2. Check for bends, scratches and other damage to the shaft.
3. Check for debris on the shaft and/or in the bristles of the brush.

❍ Inspection of the channel-opening cleaning brush

1. Check for loose or missing bristles (see Figure 7.5).
2. Check for debris on the shaft and/or in the bristles of the brush.

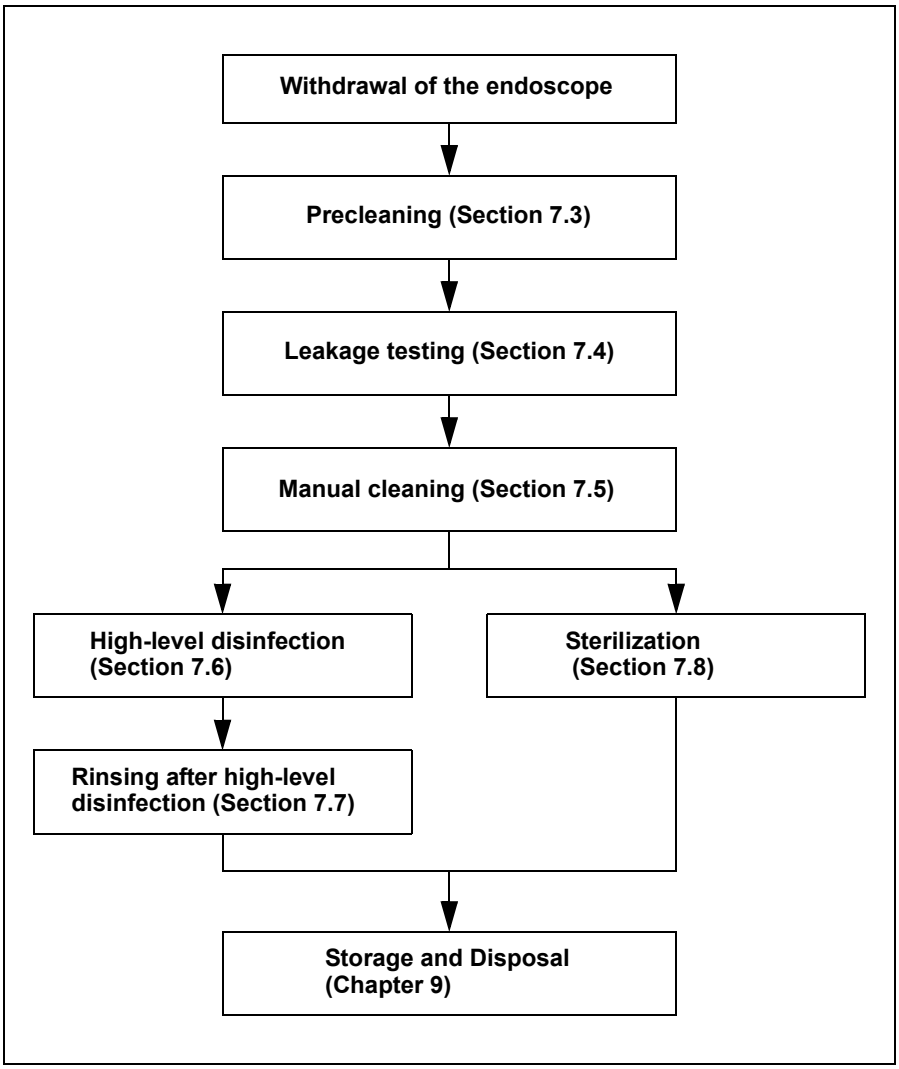
❍ Inspection of the channel cleaning wire

Check for deformations or cuts (see Figure 7.6).

7.2 Cleaning, disinfection and sterilization procedures

Clean disinfect and sterilize the endoscope according to the procedure described below.

Endoscope reprocessing summary chart


Withdrawal of the endoscope
Precleaning (Section 7.3)
Leakage testing (Section 7.4)
Manual cleaning (Section 7.5)
High-level disinfection (Section 7.6)
Sterilization (Section 7.8)
Rinsing after high-level disinfection (Section 7.7)
Storage and Disposal (Chapter 9)

WARNING

ALL channels of the endoscope, including balloon channels where fitted, MUST be cleaned and high-level disinfected or sterilized during EVERY reprocessing cycle, even if the channels were not used during the previous patient procedure. Otherwise, insufficient cleaning and disinfection or sterilization of the endoscope may pose an infection control risk to the patient and/or operators performing the next procedure with the endoscope.

7.3 Precleaning

WARNING

If the endoscope is not immediately precleaned, residual organic debris will begin to solidify and it may be difficult to effectively reprocess the endoscope.

Preclean the endoscope at the bedside in the procedure room immediately after the procedure. These steps are to be performed when suction pump is still connected to the endoscope.

Equipment needed

Prepare the following equipment.

- Personal protective equipment
- Clean, lint-free cloth
- 500 cm^3 (500 ml) containers
- Detergent solution
- Clean water (see Section 6.2)
- 30 cm^3 (30 ml) syringe

Preparation

1. Wear appropriate personal protective equipment.
2. Turn the video system center and light source OFF.
3. Prepare detergent solution at the temperature and concentration recommended by the detergent manufacturer in a 500 cm^3 (500 ml) container.
4. Prepare clean water in a 500 cm^3 (500 ml) container.

Wipe down the insertion tube

CAUTION

Handle the insertion tube carefully. Tightly gripping or sharply bending the insertion tube or bending section can stretch or severely damage the insertion tube and the covering of the bending section.

1. Remove and discard the balloon, to ensure proper cleaning of the endoscope.
2. Wipe the entire insertion tube with a clean, lint-free cloth soaked in detergent solution. Wipe from the boot toward the distal end.

Aspirate detergent solution

CAUTION

Monitor the suction bottle on the suction pump carefully to ensure that it does not overflow. Otherwise, suction pump damage could result.

1. Turn ON the suction pump.
2. Immerse the distal end of the insertion tube in detergent solution. Press the suction valve and aspirate detergent solution into the channel for 30 seconds.
3. Remove the distal end of the insertion tube from the detergent solution. Press the suction valve and aspirate air for 10 seconds.
4. Turn the suction pump, video system center, light source and ultrasound center OFF.
5. Connect the 30 cm^3 (30 ml) syringe to the irrigation port.
6. Immerse the distal end of the insertion tube in detergent solution. Pull the plunger and aspirate detergent solution into the balloon channel three times.
7. Remove the distal end of the insertion tube from the detergent solution. Pull the plunger and aspirate air through the balloon channel three times.
8. Disconnect the syringe from the endoscope.

Aspirate water

1. Turn ON the suction pump.
2. Immerse the distal end of the insertion section in clean water.
   Press the suction valve and aspirate the water into the channel for 30 seconds.
3. Remove the distal end of the insertion section from the water.
   Press the suction valve and aspirate air for 10 seconds.
4. Turn the suction pump OFF.
5. Connect the 30 cm^3 (30 ml) syringe to the irrigation port.
6. Immerse the distal end of the insertion section in the water. Pull the plunger and aspirate the water into the balloon channel three times.
7. Remove the distal end of the insertion section from the water.
   Pull the plunger and aspirate air through the balloon channel three times.
8. Disconnect the syringe from the endoscope.

Disconnect the endoscope, reusable parts and cleaning equipment

WARNING

- Do not touch the light guide of the endoscope connector immediately after removing it from the light source because it is extremely hot. Operator or patient injury may result.
- The single-use suction valve (MAJ-209) and single-use biopsy valve (MAJ-210) are intended for a single use only. Discard them after use; do not attempt to reuse or resterilize them.

1. Disconnect the suction tube from the suction connector of the suction valve.
2. Disconnect the suction valve from the endoscope (see Figure 7.8).
   When using the single-use suction valve (MAJ-209, for U.S.A.), discard it.
   When using the suction valve (MAJ-207), place it in a container of detergent solution. Clean, disinfect and sterilize the items according to the instructions given in Section 7.9, “Cleaning, disinfection and sterilization procedures for reusable parts and cleaning equipment”.

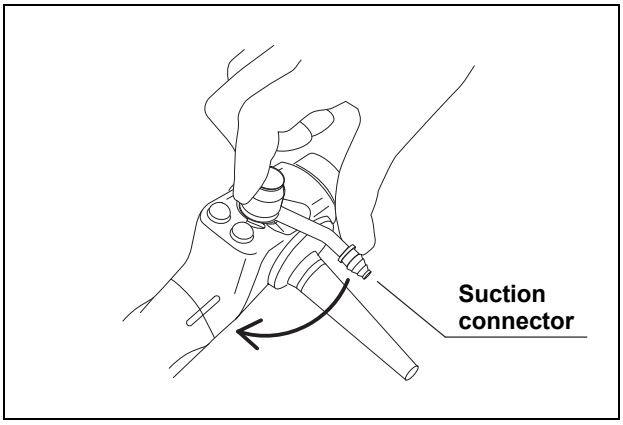


Figure 7.8

3. When using the single-use biopsy valve (MAJ-210, for U.S.A. and Europe), remove it as shown in Figure 7.9 below and discard it.
   When using the biopsy valve (MD-495), remove it and place it in a container with detergent solution. Clean, disinfect and sterilize the items according to the instructions given in Section 7.9, “Cleaning, disinfection and sterilization procedures for reusable parts and cleaning equipment”.

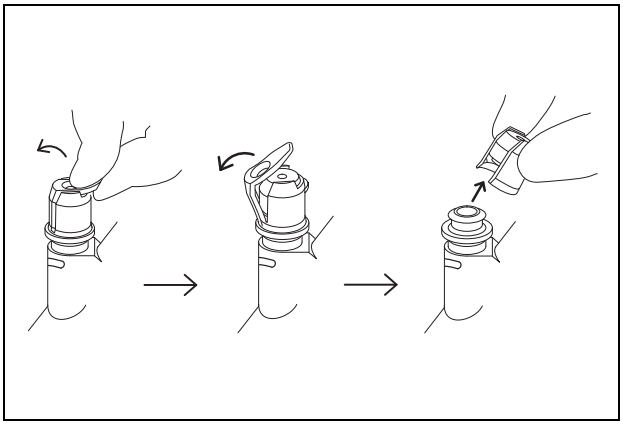


Figure 7.9

4. Disconnect the videoscope cable from the endoscope connector. Disconnect the endoscope connector from the light source.
5. Disconnect the ultrasonic connector from the ultrasound center.
6. Transport the endoscope and the container holding the other items to the reprocessing area.

7.4 Leakage testing

After precleaning, perform leakage testing on the endoscope to ensure that it is waterproof.

Equipment needed

Prepare the following equipment.

- Personal protective equipment
- Large basin
- Clean water (see Section 6.2)
- Maintenance unit or light source (MU-1 or CLV-U20, U40, 160)
- Leakage tester (MB-155)
- Water-resistant caps (MAJ-1057, MH-553)

Attaching the water-resistant caps

CAUTION

- The ultrasonic connector and the electrical connector of the endoscope are not waterproof. Before immersing or leakage testing the endoscope, always attach the water-resistant caps.
- If the exterior of the ultrasonic connector is scratched, the connector may no longer be waterproof and the seal inside the water-resistant cap may become scratched. If the ultrasonic connector is scratched, contact Olympus.
- Never immerse the water-resistant caps unless they are attached to the endoscope. Water remaining inside the water-resistant caps can be transferred to and damage the ultrasonic connector and/or the electrical connector.

1. Attach the water-resistant cap (MH-553): Position the EW or KC/TD character on the water-resistant cap at mark 2 on the electrical connector housing.
2. Align the groove on the connector with the pin on the water-resistant cap and lower the cap into position. Rotate the cap clockwise until it stops.

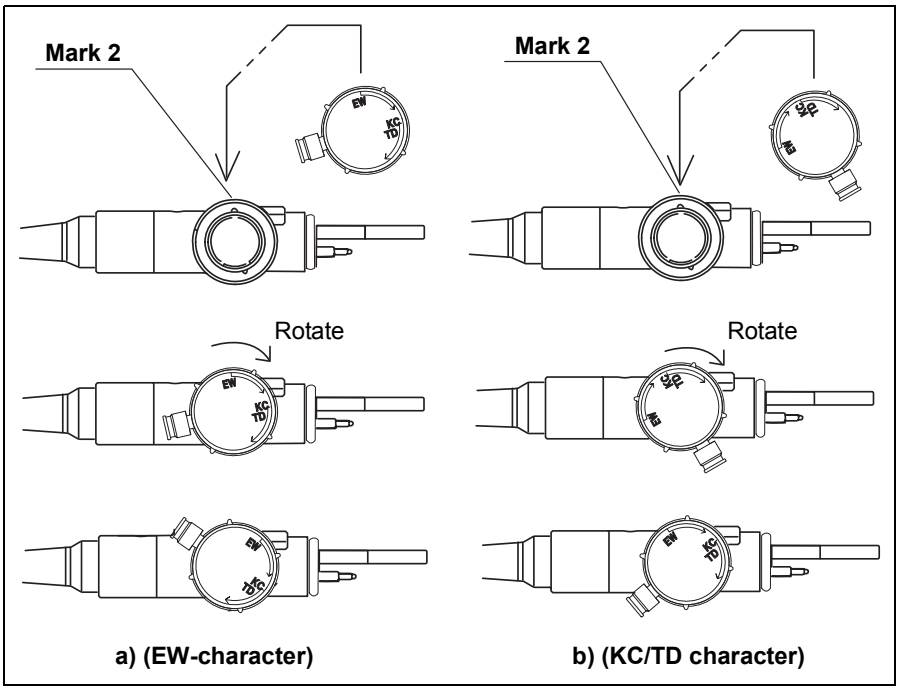


Figure 7.10

3. Attach the water-resistant cap (MAJ-1057) to the ultrasonic connector. Fasten the four latches securely (see Figure 7.11).

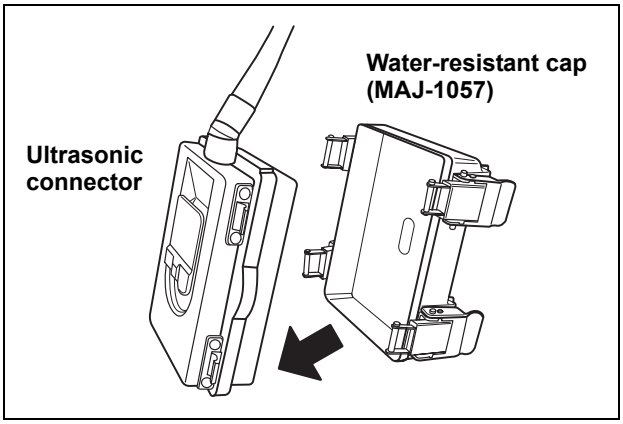


Figure 7.11

Performing the leakage test

CAUTION

- During leakage testing, a continuous series of bubbles emerging from a location on the endoscope indicates a leak at that location. This means that water will be able to penetrate the inside of the endoscope. If you locate a leak, remove the endoscope from the water and contact Olympus.
- Never connect or disconnect the water-resistant cap or the leakage tester's connector cap while immersed. Doing so could allow water to enter the endoscope and equipment damage can result.
- Rotate the leakage tester's connector cap until it stops. If it is not fully and properly attached, the endoscope's interior will not be pressurized and accurate leakage testing will be impossible.
- When connecting the leakage tester's connector cap to the water-resistant cap's venting connector, make sure that the inside of the leakage tester's connector cap and the outside of the water-resistant cap's venting connector are completely wiped and dry. Water remaining on either component may penetrate the inside of the water-resistant cap and could cause endoscope malfunction.
- Always disconnect the leakage tester connector from the light source or maintenance unit before disconnecting the leakage tester's connector cap from the venting connector. Failure to do this will not allow the endoscope to depressurize properly. This may damage the endoscope.

NOTE

When the leakage tester connector is in place, the covering of the bending section will expand as the air pressure inside the endoscope increases. This is normal.

1. Fill a basin with clean water. Use a basin which is at least 40 cm by 40 cm (16” by 16”) in size and deep enough to allow the endoscope to be completely immersed.
2. Insert the leakage tester connector into the output socket of the maintenance unit or the light source and turn the maintenance unit or the light source ON. Set the light source’s airflow regulator switch to “HIGH” or “3”.

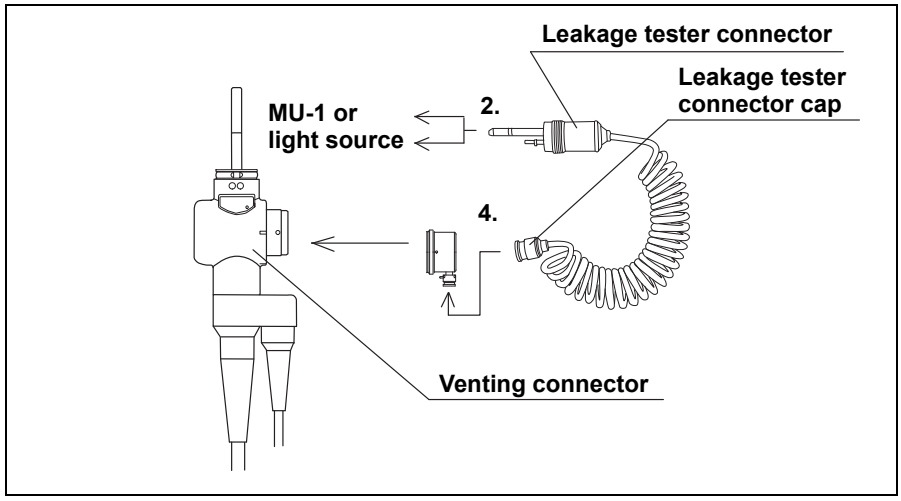


Figure 7.12

3. Confirm that the leakage tester is emitting air by gently depressing the pin located inside the leakage tester’s connector cap.
4. Connect the leakage tester’s connector cap to the venting connector (see Figure 7.12).
5. With the leakage tester connected, immerse the entire endoscope in water and observe for approximately 30 seconds while angulating the bending section. Confirm that there is no location on the endoscope from which a continuous series of bubbles emerges.
6. Remove the endoscope from the basin with the leakage tester attached.
7. Turn the maintenance unit or the light source OFF.
8. Disconnect the leakage tester from the maintenance unit or the light source.
9. Wait 30 seconds, or until the covering of the bending section contracts to its pre-expansion size. Disconnect the leakage tester’s connector cap from the venting connector.
10. Thoroughly dry the leakage tester.

7.5 Manual cleaning

After completing the leakage test, perform manual cleaning according to the procedures described below.

In case of excessive bleeding and/or delayed reprocessing, perform “Presoak for excessive bleeding and/or delayed reprocessing” on page 90 and follow the procedure described below.

Equipment needed

Prepare the following equipment.

- Personal protective equipment
- Clean, lint-free cloth
- Large basins
- Low-foaming detergent solution
- Clean water (see Section 6.2)
- Suction pump
- Suction cleaning adapter (MAJ-222)
- Channel cleaning wire (BW-16C)
- Channel cleaning brush (BW-15B)
- Channel-opening cleaning brush (MH-507)
- Soft brush
- 30 cm^3 (30 ml) syringe

CAUTION

To prevent damage to the endoscope, never immerse the endoscope together with objects such as EndoTherapy accessories.

Preparation

1. Wear appropriate personal protective equipment.
2. Fill a basin with clear water. Use a basin which is at least 40 cm by 40 cm (16” by 16”) in size and deep enough to allow the endoscope to be completely immersed.

Cleaning the external surface

1. Immerse the endoscope in the detergent solution.
2. With the endoscope immersed, use a soft brush or lint-free cloth to thoroughly brush and wipe all external surfaces of the endoscope.

Brushing the channels

WARNING

- To avoid splattering detergent solution when the channel cleaning brush is pulled out, keep the endoscope submerged.
- The cleaning brushes are consumable items that are subject to wear. If the brush head is bent or kinked during use, it may come off. Confirm that the brushes are free from any damages or other irregularities before and after each use. Should a part of the brush comes off, immediately retrieve it and carefully confirm that it is not left inside the channel of the endoscope by passing a new cleaning brush or other EndoTherapy accessory. Any parts left in the channel may drop into the patient during the procedure. Depending on its location, the missing part may not be recoverable by passing a new brush or other equipment through the channel. In this case, contact Olympus.
- When using the single use channel cleaning brush (BW-201B), withdraw the instrument straight from the suction channel and do not rub its shaft against the external opening of the suction cylinder. Otherwise, shaft may be shaved and shaft's shavings may enter into the endoscope's suction channel. However, if the suction channel is cleaned according to this manual, the shavings will not remain in the suction channel.

While the endoscope is submerged, clean the channels as follows (see Figure 7.13).

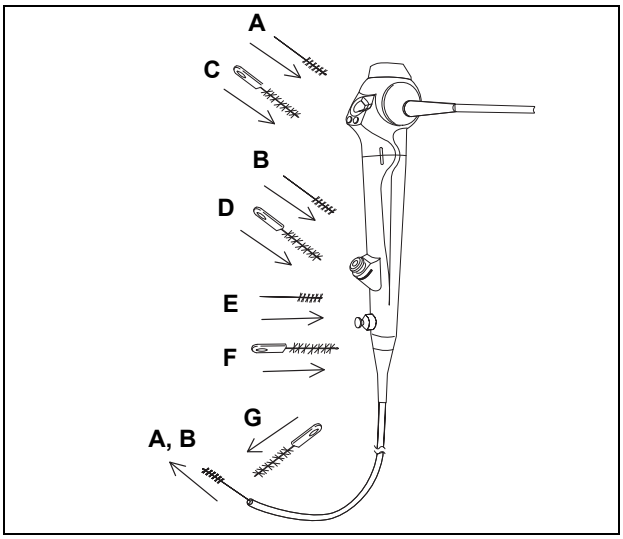


Figure 7.13

❍ Brushing the channel through the suction cylinder (location A)

1. Straighten the endoscope's bending section. Grip the channel cleaning brush (BW-15B) at a point 3 cm from the bristles.
2. Insert the channel cleaning brush into the suction cylinder as illustrated by A in Figure 7.13. Using short strokes, feed the brush through the insertion tube until it emerges from the distal end of the endoscope.
3. Clean the bristles with your fingertips in the detergent solution. Carefully pull the brush out through the channel.
4. Repeat until all debris is removed.

❍ Brushing the channel through the instrument channel port (location B)

1. Grip the channel cleaning brush (BW-15B) 3 cm from the bristles.
2. Insert the channel cleaning brush into the instrument channel port as illustrated by B in Figure 7.13. Using short strokes, feed the brush through the channel until it emerges from the distal end of the endoscope.
3. Clean the bristles with your fingertips in the detergent solution. Carefully pull the brush out through the channel.
4. Clean the bristles in the detergent solution again.

5. Repeat until all debris is removed.

❍ Brushing the suction cylinder (location C)

CAUTION

When inserting the channel-opening cleaning brush into the suction cylinder, do not forcibly insert the brush beyond the middle of the bristled section. Otherwise, the brush may become stuck in the suction cylinder.

1. Insert the channel-opening cleaning brush (MH-507) into the suction cylinder as illustrated by C in Figure 7.13 until half of the bristled section is inserted.
2. Turn the inserted brush once.
3. Pull the brush out and clean the bristles in the detergent solution.
4. Repeat until all debris is removed.

❍ Brushing the instrument channel port (location D)

1. Insert the channel-opening cleaning brush (MH-507) into the instrument channel port until the brush handle touches the channel opening as illustrated by D in Figure 7.13.
2. Turn the inserted brush once.
3. Pull the brush out and clean the bristles in the detergent solution.
4. Repeat until all debris is removed.

❍ Cleaning the balloon channel in the insertion tube (location E)

1. Grip the channel cleaning wire (BW-16C) 1.5 cm from the distal end.
2. Insert the channel cleaning wire into the irrigation port as illustrated by E in Figure 7.13. Using short strokes, feed the wire through the insertion tube until it stops.
3. Carefully pull the wire out through the channel.
4. Clean the wire with your fingertips in the detergent solution again.
5. Repeat until all debris is removed.

❍ Brushing the irrigation port (location F)

1. Insert the channel-opening cleaning brush (MH-507) into the irrigation port until it stops as illustrated by F in Figure 7.13.
2. Turn the inserted brush once.
3. Pull the brush out and clean the bristles in the detergent solution.
4. Repeat until all debris is removed.
5. Soak all cleaning brushes in detergent solution, then reprocess them as described in Section 7.9, “Cleaning, disinfection and sterilization procedures for reusable parts and cleaning equipment”.

❍ Brushing the balloon grooves (location G)

Brush the balloon grooves with channel-opening cleaning brush (MH-507) until all debris is removed.

Aspirating detergent solution into the instrument/suction channels

1. Attach the suction cleaning adapter’s port cap to the instrument channel port. Attach the suction cylinder cap to the suction cylinder.
2. Connect the suction tube from the suction pump to the suction opening of the suction cleaning adapter.
3. Turn ON the suction pump.
4. Immerse the endoscope’s distal end in the detergent solution.
5. Depress the suction valve and aspirate detergent solution for approximately 30 seconds.
6. Turn OFF the suction pump.
7. Disconnect the suction tube from the suction cleaning adapter.

Flushing detergent solution into the instrument/suction/balloon channels

1. Disconnect the suction tube from the suction cleaning adapter. Completely immerse the endoscope and suction cleaning adapter.
2. Attach the 30 cm^3 (30 ml) syringe to the suction opening on the adapter.
3. Withdraw the plunger of the syringe to fill the suction cleaning adapter and the channel with detergent solution (see Figure 7.14).

4. Connect the syringe to the irrigation port and depress the plunger to fill the balloon channel with detergent solution.
5. With the endoscope and suction cleaning adapter completely immersed in detergent solution, disconnect the suction cleaning adapter and syringe.

CAUTION

Do not pull the tubes of the suction cleaning adapter when disconnecting the suction cleaning adapter from the endoscope.

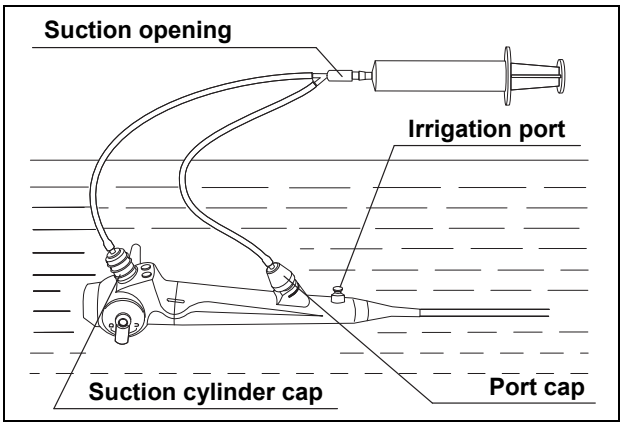


Figure 7.14

Soaking the endoscope and all equipment in detergent solution

1. Using a lint-free cloth, wipe all debris from the endoscope's external surface while the endoscope is immersed in the detergent solution.
2. Using the channel-opening cleaning brush (MH-507), brush the balloon grooves at the distal end of the endoscope.
3. Cover the basin with a tight fitting lid to minimize the release of detergent vapors.
4. Soak the endoscope all equipment for the amount of time and at the temperature recommended by the detergent manufacturer.

Removing and rinsing the endoscope and all equipment

1. Remove the endoscope and all equipment from detergent solution and place them in clean water.
2. Gently agitate them to thoroughly rinse.

Removing detergent solution from the instrument/suction/balloon channels

1. Attach the suction cleaning adapter to the endoscope and the suction tube.
2. Turn ON the suction pump. Aspirate clean water for 30 seconds.
3. Remove the endoscope, together with the suction cleaning adapter, from the water. Aspirate air for 20 seconds.
4. Turn OFF the suction pump.
5. Detach the suction cleaning adapter from the endoscope.
6. Detach the suction tube from the suction cleaning adapter.
7. Connect the syringe to the irrigation port and depress the plunger.
8. Flush 30 cm^3 (30 ml) of clean water through the balloon channel 5 times and flush 30 cm^3 (30 ml) of air through the balloon channel 5 times to expel all water.
9. Disconnect the syringe from the endoscope.

Dry external surfaces

1. Using a lint-free cloth, thoroughly wipe and dry the external surfaces of the endoscope and suction cleaning adapter.
2. Inspect the endoscope for residual debris. Should debris remain, repeat the procedures given in this section.

Presoak for excessive bleeding and/or delayed reprocessing

CAUTION

Follow the steps below only in case of excessive bleeding and/or delayed reprocessing: unnecessary immersion should be avoided. Consecutive extended immersions may damage the endoscope.

Preclean and perform a leakage test on the endoscope as described in Section 7.3, “Precleaning” and Section 7.4, “Leakage testing”.

1. Fill a basin with detergent solution at a temperature and concentration recommended by the detergent manufacturer. Use a basin which is at least 40 cm by 40 cm (16” by 16”) in size and deep enough to allow the endoscope to be completely immersed.
2. Carefully coil the endoscope’s insertion tube and universal cord and completely immerse the endoscope in the detergent solution.

CAUTION

Do not coil the insertion tube, universal cord and ultrasonic cable with a diameter of less than 12 cm. Equipment damage can result.

3. Connect the suction cleaning adapter to the endoscope. Completely immerse the endoscope in the detergent solution.
4. Attach a 30 cm^3 (30 ml) syringe to the suction cleaning adapter. Withdraw the plunger of the syringe to fill the channel and suction cleaning adapter with detergent solution.
5. Connect the syringe to the irrigation port and pull the plunger to fill the balloon channel with detergent solution.
6. With the endoscope, suction cleaning adapter and syringe completely immersed in detergent solution, disconnect the suction cleaning adapter and syringe.

CAUTION

To prevent damage, do not pull the tubes of the suction cleaning adapter when disconnecting it from the endoscope. Always pull the caps.

7. Soak the endoscope for 1 hour at the temperature recommended by the detergent manufacturer.
8. Remove the endoscope from the detergent solution.
9. After soaking the endoscope, manually clean it following the procedures described in this section 7.5, “Manual cleaning”, then disinfect or sterilize the endoscope following the procedures described in Section 7.6, “High-level disinfection” or Section 7.8, “Sterilization”.

7.6 High-level disinfection

WARNING

All disinfection steps should be performed with the endoscope and all equipment completely immersed in disinfectant solution. If the equipment is connected or disconnected while not immersed, disinfectant solution may not adequately contact all surfaces of the equipment. As a result, the effectiveness of disinfection may be reduced.

After manual cleaning, disinfect the endoscope according to the procedure described below.

Equipment needed

Prepare the following equipment.

- Personal protective equipment
- Clean, lint-free cloths
- Large basin
- Suction pump
- Disinfectant solution
- Suction cleaning adapter (MAJ-222)
- 30 cm^3 (30 ml) syringe

Preparation

1. Wear appropriate personal protective equipment.
2. Fill a basin with disinfectant solution at the temperature and concentration recommended by the disinfectant manufacturer. Use a basin which is at least 40 cm by 40 cm (16” by 16”) in size and deep enough to allow the endoscope to be completely immersed.

Flushing disinfectant solution into the instrument/suction/balloon channels

WARNING

Completely remove air bubbles from all channels. Disinfection effects can not be obtained it bubbles remain in the channels.

NOTE

Air bubble removal can be facilitated by injecting disinfectant solution into channels with strong force.

1. Connect the suction cleaning adapter to the endoscope.
2. Attach the 30 cm^3 (30 ml) syringe to the suction cleaning adapter.
3. Immerse the endoscope and all equipment in disinfectant solution. Pull the plunger of the syringe to fill the channel and suction cleaning adapter with disinfectant solution.
4. Connect the syringe to the irrigation port and pull the plunger to fill the balloon channel with disinfectant solution.
5. With the endoscope and the suction cleaning adapter completely immersed in disinfectant solution, disconnect the suction cleaning adapter from the endoscope.

Soaking the endoscope and all equipment in disinfectant solution

1. If air bubbles adhere to the surfaces of the endoscope and suction cleaning adapter, remove them using a clean, lint-free cloth.
2. Cover the basin with a tight fitting lid to minimize the release of disinfectant vapors.
3. Soak the endoscope and all equipment in the disinfectant solution for the amount of time and at the temperature recommended by the disinfectant manufacturer.

Removing the endoscope and all equipment from disinfectant solution

1. Before removing the endoscope from the disinfectant solution, attach the suction cleaning adapter to the endoscope.
2. Attach the 30 cm^3 (30 ml) syringe to the suction cleaning adapter and flush the channels with 90 cm^3 (90 ml) of air.
3. Connect the syringe to the irrigation port and flush 30 cm^3 (30 ml) of air through the balloon channel 5 times.
4. Remove the endoscope and all equipment from the disinfectant solution.
5. Disconnect all equipment from the endoscope.

7.7 Rinsing after high-level disinfection

WARNING

After reprocessing, purge the channels of the endoscope to thoroughly dry them. Otherwise, bacteria may proliferate in the channels and pose an infection-control risk to the patient and/or operators performing the next procedure with the endoscope.

After high-level disinfection, rinse the endoscope to the procedures described below.
Use water of appropriate microbiological quality. Once removed from disinfectant solution, the instrument must be thoroughly rinsed with sterile water to remove any disinfectant residue. If sterile water is not available, fresh potable tap water or water which has been processed (e.g. filtered) to improve its microbiological quality may be used with a 70% ethyl or isopropyl alcohol rinse (see “Non-sterile water rinse and alcohol flush” on page 97). Consult with your hospital’s infection control committee.

Equipment needed

Prepare the following equipment.

- Personal protective equipment
- Sterile, lint-free cloths
- Large basin
- Sterile water (for sterile water rinse)
- Clean water (non-sterile water)
- Suction pump
- 70% ethyl or isopropyl alcohol
- 30 cm^3 (30 ml) syringe
- Suction cleaning adapter (MAJ-222)
- Sterile cotton swabs

If sterile water is not available prepare the following equipment.

- Clean water (for non-sterile water rinse)
- 70% ethyl or isopropyl alcohol
- Sterile cotton swabs
- Small basin

CAUTION

Alcohol is flammable. Handle with care.

Ware appropriate personal protective equipment.

❍ Sterile water rinse

1. Fill a basin with sterile water. Use a basin which is at least 40 cm by 40 cm (16” by 16”) in size and deep enough to allow the endoscope to be completely immersed.
2. Immerse the endoscope and suction cleaning adapter in sterile water. Using a clean, lint-free cloth, thoroughly rinse and wipe all external surfaces.
3. Connect the suction cleaning adapter and suction pump to the endoscope.
4. Turn ON the suction pump.
5. Aspirate sterile water for 30 seconds.
6. Remove the endoscope from the sterile water and aspirate air for 60 seconds.
7. Turn OFF the suction pump.

8. Immerse the distal end of the insertion tube in the sterile water. Connect the 30 cm^3 (30 ml) syringe to the irrigation port.
9. Pull the plunger and aspirate 30 cm^3 (30 ml) of the sterile water through the balloon channel. Repeat this procedure 5 times.
10. Remove the distal end of the insertion tube from the sterile water and flush 30 cm^3 (30 ml) of air through the balloon channel 5 times to expel all water.
11. Hold the control section with the instrument channel port pointing down and disconnect the suction cleaning adapter from the endoscope (see Figure 7.15).

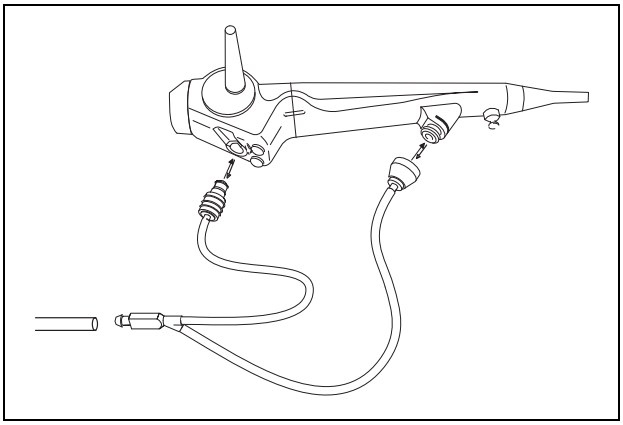


Figure 7.15

12. Disconnect the syringe from the endoscope.
13. Wipe and dry the endoscope and suction cleaning adapter with a sterile, lint-free cloth.
14. Dry the endoscope and suction cleaning adapter.
15. Store the components following the instructions given in Chapter 9, “Storage and Disposal”.

NOTE

Flushing the channels with 70% ethyl or isopropyl alcohol after rinsing them with sterile water facilitates drying the inside of the channels.

❍ Non-sterile water rinse and alcohol flush

CAUTION

Alcohol is flammable. Handle with care.

1. Aspirate non-sterile water and air following the procedures given in “Sterile water rinse” on page 95.
2. Turn ON the suction pump.
3. Immerse the distal end of the endoscope in 70% ethyl or isopropyl alcohol. Aspirate alcohol for 5 seconds.
4. Remove the distal end of the endoscope from the alcohol and aspirate air for 20 seconds.
5. Turn OFF the suction pump.
6. Immerse the distal end of the endoscope in 70% ethyl or isopropyl alcohol. Connect the 30 cm^3 (30 ml) syringe to the irrigation port.
7. Pull the plunger and aspirate 30 cm^3 (30 ml) of alcohol through the balloon channel. Repeat this procedure 5 times.
8. Remove the distal end of the endoscope from the alcohol and flush 30 cm^3 (30 ml) of air through the balloon channel 5 times.
9. Hold the control section with the instrument channel port pointing down and disconnect the suction cleaning adapter from the endoscope (see Figure 7.15).
10. Disconnect the syringe from the endoscope.
11. Using a sterile, lint-free cloth, thoroughly wipe and dry the external surfaces of the endoscope and all equipment.
12. Using a sterile, lint-free cloth moistened with alcohol, thoroughly wipe the external surfaces of the endoscope and all equipment.
13. Using sterile cotton swabs, dry the inside of the suction cylinder and instrument channel port.
14. Dry the endoscope and suction cleaning adapter.
15. Store the components following the instructions given Chapter 9, “Storage and Disposal”.

7.8 Sterilization

ETO gas sterilization

As an alternative to high-level disinfection, the endoscope can be sterilized by ethylene oxide (ETO) gas. After performing manual cleaning and drying as described in Section 7.3, “Precleaning” and Section 7.5, “Manual cleaning”, follow the procedures given below.

CAUTION

- Exceeding the recommended parameters may cause equipment damage.
- If ETO gas sterilization is performed while the water-resistant caps are attached, the covering of the bending section can be damaged.
- The water-resistant caps cannot be ETO gas sterilized and may be damaged if it is subjected to ETO gas sterilization. If the water-resistant caps is connected to the endoscope be sure to remove the water-resistant caps from the endoscope before proceeding to ETO gas sterilization.

1. Dry the endoscope before ETO gas sterilization.
2. Remove the water-resistant caps before ETO gas sterilization.
3. Seal the instrument in a package appropriate for ETO gas sterilization according to your hospital’s protocol.
4. Sterilize the package according to the recommended ETO gas exposure parameters as described in Section 6.6, “ETO gas sterilization” and the sterilizer manufacturer’s instructions.
5. Aerate the components following the minimum aeration parameters specified in Section 6.6, “ETO gas sterilization”.
6. Store the components following the instructions given in Chapter 9, “Storage and Disposal”.

7.9 Cleaning, disinfection and sterilization procedures for reusable parts and cleaning equipment

This section includes the cleaning, disinfection and sterilization procedures for the reusable parts and reprocessing equipment listed below. For all other parts, refer to their respective instruction manuals. For compatible reprocessing methods, refer to Section 6.1, “Compatibility summary”.

Equipment needed

Prepare the following equipment.

- Personal protective equipment
- Soft brush
- Clean, lint-free cloths
- Sterile, lint-free cloths
- Large basins
- Detergent solution
- Disinfectant solution
- Clean water (non-sterile water)
- Sterile water (for sterile water rinse)
- Small container
- 70% ethyl or isopropyl alcohol
- 30 cm^3 (30 ml) syringe

❍ Reusable parts which are normally reprocessed with the endoscope

- Suction cleaning adapter (MAJ-222)
- Water resistant caps (MH-553 and MAJ-1057)

❍ Reusable parts which are normally reprocessed separately from the endoscope

- Mouthpiece (MA-651)
- Channel cleaning wire (BW-16C)
- Channel cleaning brush (BW-15B)
- Channel-opening cleaning brush (MH-507)
- Suction valve (MAJ-207)
- Biopsy valve (MD-495)
- Balloon applicator (MAJ-1352)

Preparation

Wear appropriate personal protective equipment.

Disassembling the suction valve (MAJ-207, not for U.S.A.)

1. Remove the valve seal from the main body (see Figure 7.16).
2. Remove the piston and spring from the main body (see Figure 7.16).
3. Remove the piston from the spring (see Figure 7.16).

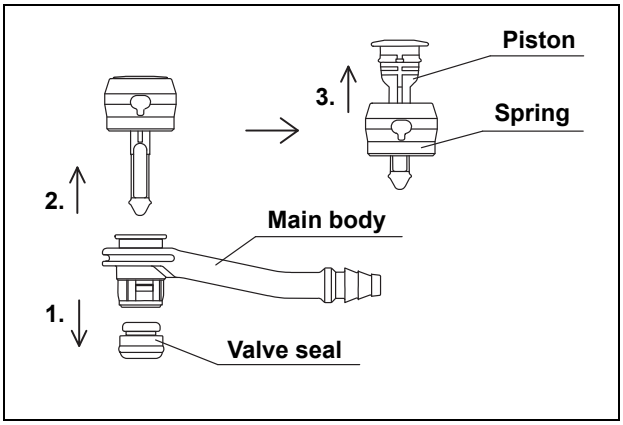


Figure 7.16

NOTE

The spring, valve seal, main body, and piston are colored gray. Use the color as a guide to distinguish these components from other equipment.

Manual cleaning

CAUTION

Make sure that the items immersed in detergent solution do not contact one another.

1. Fill a small basin with clean water. Use a basin which is deep enough to allow all equipment to be completely immersed.
2. Fill a basin with low-foaming detergent solution at the temperature and concentration recommended by the detergent manufacturer. Use a basin which is deep enough to allow all equipment to be completely immersed.
3. Remove the cap from the body of the biopsy valve, before immersing in the detergent solution (for reusable biopsy valve MD-495 only).
4. Immerse all equipment in the detergent solution.

5. Using a soft brush or clean lint-free cloth, clean external surfaces of all equipment in detergent solution.
6. Using a soft brush or clean lint-free cloth, clean the inside of the mouthpiece in detergent solution.
7. Using the channel cleaning brush, thoroughly brush the openings of the disassembled suction valve, until no debris can been seen (for reusable suction valve MAJ-207 only).
8. Using the channel cleaning brush, thoroughly brush the interior and openings of the biopsy valve. Clean the bristle of the cleaning brushes thoroughly while the brushes are immersed (for reusable biopsy valve MD-495 only).
9. Using the 30 cm^3 (30 ml) syringe, flush the interior and openings of all equipment until no bubbles exit the distal end of the endoscope.
10. Rub the bristles of the channel cleaning brush and channel-opening cleaning brush to remove all air bubbles.
11. Using the 30 cm^3 (30 ml) syringe, flush the inside of the suction cleaning adapter with the detergent solution while the adapter is immersed.
12. Cover the basin with a tight fitting lid to minimize the diffusion of detergent vapors. Soak all equipment at the temperature and concentration recommended by the detergent manufacturer.
13. Remove all equipment from the detergent solution and inspect it. If debris remains, ultrasonically clean at 33 – 48 kHz for 5 minutes.
14. Immerse all equipment in the clean water.
15. Gently agitate all equipment to thoroughly rinse.
16. Rub the bristles of the channel cleaning brush and channel-opening cleaning brush to remove all air bubbles.
17. Using the 30 cm^3 (30 ml) syringe, flush the inside of the suction cleaning adapter thoroughly with clean water while it is immersed.
18. Remove the suction cleaning adapter from the clean water and remove all water from it.
19. Remove all equipment from the clean water.
20. Using a sterile, lint-free cloth, thoroughly wipe and dry all external surfaces.

High-level disinfection

WARNING

- Completely remove all air bubbles from all equipment. Optimum disinfection cannot be obtained if bubbles remain on the equipment.
- All disinfection steps should be performed with all equipment completely immersed. If any part of the equipment is not immersed completely, disinfectant solution may not adequately contact all surfaces.

1. Fill a basin with disinfectant solution at the temperature and concentration recommended by the disinfectant manufacturer. Use a basin which is deep enough to allow all equipment to be completely immersed.
2. Immerse all equipment in the disinfectant solution.
3. Using a lint-free cloth and/or 30 cm^3 (30 ml) syringe, wipe and/or flush all surfaces with the disinfectant solution to remove all air bubbles.
4. Using the 30 cm^3 (30 ml) syringe, flush the interior and recessed parts of the equipment while they are immersed. Ensure that all air bubbles are expelled.
5. Using the 30 cm^3 (30 ml) syringe, flush the recessed parts of the biopsy valve with disinfectant solution while the valve is immersed. Ensure that all air bubbles are expelled (for reusable biopsy valve MD-495 only).
6. Rub the bristles of the channel cleaning brush and channel-opening cleaning brush to remove all air bubbles.
7. Using the 30 cm^3 (30 ml) syringe, flush the inside of the suction cleaning adapter thoroughly with disinfectant solution while it is immersed.
8. Cover the basin with a tight fitting lid to minimize the release of disinfectant vapor. Soak all equipment at the temperature and concentration recommended by the disinfectant manufacturer.
9. Remove the suction cleaning adapter from the disinfectant solution and remove all disinfectant solution from it.
10. Remove all equipment from the disinfectant solution.

Rinsing after high-level disinfection

After high-level disinfection, rinse all equipment according to the procedures described below.
Use water of appropriate microbiological quality. Once removed from disinfectant solution, the instrument must be thoroughly rinsed with sterile water to remove any disinfectant residue. If sterile water is not available, fresh potable tap water or water which has been processed (e.g. filtered) to improve its microbiological quality may be used with 70% ethyl or isopropyl alcohol rinse (see "Non-sterile water rinse and alcohol flush" on page 104). Consult with your hospital's infection control committee.

CAUTION

Alcohol is flammable. Handle with care.

❍ Sterile water rinse

1. Fill a small basin with sterile water. Use a basin which is deep enough to allow all equipment to be completely immersed.
2. Immerse all equipment in the sterile water.
3. Gently agitate all equipment to thoroughly rinse.
4. Using the 30 cm^3 (30 ml) syringe, flush the interior and recessed parts of all equipment with sterile water while immersed.
5. Rub the bristles of the channel cleaning brush and channel-opening cleaning brush to remove all air bubbles.
6. Attach the 30 cm^3 (30 ml) syringe to the suction cleaning adapter and flush the adapter with 30 cm^3 (30 ml) of sterile water while immersed. Ensure that all bubbles are expelled.
7. Remove the suction cleaning adapter from the sterile water and remove all sterile water from it.
8. Remove all equipment from the sterile water.
9. Use a sterile, lint-free cloth to thoroughly wipe and dry all external surfaces.

NOTE

Flushing the channels with 70% ethyl or isopropyl alcohol after rinsing them with sterile water facilitates drying inside the channels.

10. Dry all equipment.
11. Store the components following the instructions given in Chapter 9, "Storage and Disposal".

Non-sterile water rinse and alcohol flush

1. Fill a small basin with clean water.
2. Immerse all equipment in clean water and follow all procedures described in “Sterile water rinse” on page 103.
3. Fill a small basin with 70% ethyl or isopropyl alcohol.
4. Immerse all equipment in the alcohol.
5. Gently agitate the equipment.
6. Using the 30 cm^3 (30 ml) syringe, flush the interior and recessed parts of all equipment with alcohol to remove all air bubbles.
7. Rub the bristles of the channel cleaning brush and channel-opening cleaning brush to remove all air bubbles.
8. Attach the 30 cm^3 (30 ml) syringe to the suction cleaning adapter and flush the adapter with 30 cm^3 (30 ml) of alcohol to remove all air bubbles.
9. Remove the suction cleaning adapter from the alcohol and remove all alcohol from it.
10. Remove all equipment from the alcohol.
11. Using a sterile, lint-free cloth, thoroughly wipe and dry all external surfaces.
12. Dry all equipment.
13. Store the components following the instructions given in Chapter 9, “Storage and Disposal”.

Sterilization

❍ ETO gas sterilization

CAUTION

The cleaning brushes are not compatible with ETO gas sterilization.

After cleaning and drying as described in “Manual cleaning” on page 100, follow the procedures given below.

1. Seal the individual parts or equipment separately in packages appropriate for ETO gas sterilization according to your hospital’s protocol.
2. Sterilize the packages following the recommended ETO gas exposure parameters as described in Section 6.6, “ETO gas sterilization” and the sterilizer manufacturer’s instructions.
3. Aerate the components following the minimum aeration parameters specified in Section 6.6, “ETO gas sterilization”.
4. Store the components following the instructions given in Chapter 9, “Storage and Disposal”.

❍ Steam sterilization (autoclaving)

After cleaning as described in “Manual cleaning” on page 100, steam sterilize (autoclave) following the procedure given below.

WARNING

- Before taking the equipment package out of the autoclave, let it cool down to room temperature. Otherwise, it may cause burns.
- Effective sterilization will not be possible if items are packed tightly together in the autoclave; always pack items loosely.
- Inspect each equipment package for openings, tears or other damage. If the equipment package is open or damaged, seal the equipment in new package and re-sterilize it as described below.
- Allow the packages to dry within the autoclave, using the autoclave’s drying cycle (if available) or by opening the door of the autoclave and allowing the packages to air-dry. Handling a wet package can compromise its sterility.

1. Seal the individual parts or equipment separately in packages appropriate for steam sterilization (autoclaving) according to your hospital’s protocol.

2. Steam sterilize the packages following the recommended steam sterilization (autoclaving) exposure parameters as described in Section 6.7, “Steam sterilization (autoclaving) of accessories” and the sterilizer manufacturer’s instructions.

CAUTION

Sudden changes in temperature may damage the instruments.

3. Following steam sterilization (autoclaving), let all components gradually cool down to room temperature.

4. Store the components following the instructions given in Chapter 9, “Storage and Disposal”.

Assembling the suction valve (MAJ-207, not for U.S.A.)

1. Press the valve seal into the main body (see Figure 7.17).

2. Attach the spring to the main body (see Figure 7.17).

3. Insert the piston into the assembly and press it down a few times (see Figure 7.17).

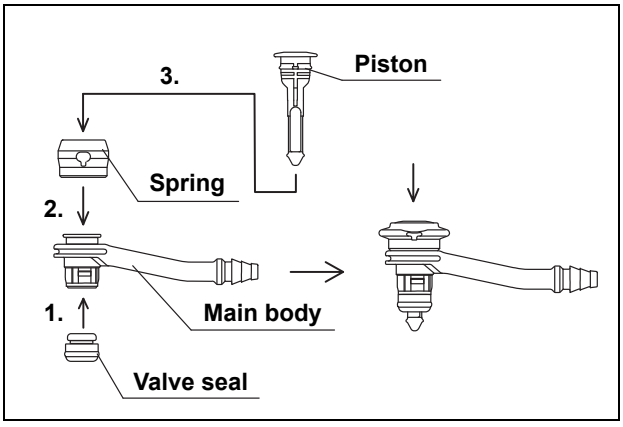


Figure 7.17

Chapter 8 Cleaning and Disinfection Equipment

The endoscope is compatible with some endoscope washers recommended by Olympus. Refer to the respective instruction manual for details on operation. Cleaning and disinfection of an endoscope in an endoscope reprocessor requires a cleaning tube that matches the endoscope model. The applicable cleaning tubes for each endoscope model are listed in the “Applicable Endoscope and Cleaning Tube Table” of the endoscope reprocessor, but note that this table is updated every time a new product model is released.
If your endoscope model is not listed in this table, please contact Olympus. It is also recommended to order the latest version of this table from the manufacturer.

WARNING

- Thoroughly clean the endoscope according to Chapter 7, “Cleaning, Disinfection and Sterilization Procedures” before cleaning and disinfection of an endoscope in an endoscope reprocessor. If the endoscope reprocessor is used with an endoscope with a large amount of debris attached to it, cleaning and disinfection may pose an infection-control risk to the patients and/or operators who perform the next procedure with it. Note that cleaning of the endoscope becomes difficult if debris is allowed to solidify because of a delay before cleaning following the procedure. Refer to the instruction manual of endoscope reprocessor for details.

- Olympus confirms validation of the endoscope reprocessors recommended by Olympus only. If using endoscope reprocessor that are not recommended by Olympus, the endoscope reprocessor manufacturers are responsible for validation of the endoscope reprocessor with the endoscope models listed in its intended use statement. If using an endoscope reprocessor, confirm that it is capable of reprocessing endoscope including all channels. If there are channels and/or other parts which cannot be cleaned and high-level disinfected by the endoscope reprocessor, have to undergo manual cleaning and high-level disinfection or sterilization as described in Chapter 7, “Cleaning, Disinfection and Sterilization Procedures” after using the endoscope reprocessor. Otherwise, insufficient cleaning and disinfection or sterilization of the endoscope may pose an infection control risk to the patient and/or operators performing the next procedure with the endoscope. If you are uncertain as to the ability of your endoscope reprocessor to clean and high-level disinfect endoscope including all channels, contact the endoscope reprocessor supplier for specific instructions and/or connectors.
- Use connectors special to each model when cleaning and disinfecting the endoscope with the endoscope reprocessor. Otherwise, insufficient cleaning and disinfection or sterilization of the endoscope may pose an infection control risk to the patient and/or operators performing the next procedure with the endoscope. The applicable connectors for each endoscope model should be listed in the automated endoscope reprocessor instruction manual. If your endoscope model is not listed in this table, please contact the manufacturer of the endoscope reprocessor.

Chapter 9 Storage and Disposal

9.1 Storage of the endoscope

WARNING

- The storage cabinet must be clean, dry, well ventilated and maintained at ambient temperature. Storing the endoscope in direct sunlight, at high temperatures, in high humidity or exposed to X-rays may damage the endoscope and/or present an infection control risk.
- Prior to storage, detach all removable parts from the endoscope. Removing the suction valve and biopsy valve will allow air to circulate through the channel of the endoscope and will assist drying.
- Do not store the endoscope in the carrying case. Use the carrying case only for shipping the endoscope. Routinely storing the endoscope in a humid, non-ventilated environment, such as the carrying case, may present an infection control risk.
- The package containing the balloons also contains a deoxidizer to maintain a deoxygenated condition until the package are opened. After the package is opened, the balloons will gradually deteriorate. To minimize deterioration, always keep the package sealed.

1. Detach all equipment from the endoscope.
2. Before storage of a high-level disinfected endoscope, thoroughly dry all parts of the endoscope (especially all internal lumens, the distal end and lenses) and all accessories.
3. Using a cotton swab moistened with 70% ethyl or isopropyl alcohol, carefully wipe the lenses at the distal end.
4. Hang the endoscope in the storage cabinet with the distal end hanging freely. Make sure that the insertion tube hangs vertically and as straight as possible.

9.2 Storage of reusable parts and reprocessing equipment

1. Confirm that all reusable parts and reprocessing equipment are dry.
2. Store all reusable parts loosely in a storage cabinet.
3. Store all reprocessing equipment in a container, then place the container in the storage cabinet.

9.3 Disposal

When disposing of this product, or any of its components, follow all applicable national laws and guidelines.

Chapter 10 Troubleshooting

If the endoscope is visibly damaged, does not function as expected or is found to have irregularities during the inspection described in Chapter 3, “Preparation and Inspection”, do not use the endoscope. Contact Olympus.
Some problems that appear to be malfunctions may be correctable by referring to Section 10.1, “Troubleshooting guide”. If the problem cannot be resolved by the described remedial action, stop using the endoscope and send it to Olympus for repair.
Olympus does not repair accessory parts. If an accessory part becomes damaged, contact Olympus to purchase a replacement.

WARNING

Never use the endoscope on a patient if an abnormality is suspected. Damage or irregularity in the instrument may compromise patient or user safety and may result in more severe equipment damage.

If any abnormality in the function of the endoscope and/or endoscopic image is suspected during use, stop the examination immediately and carefully withdraw the endoscope from the patient as described in Section 10.2, “Withdrawal of the endoscope with an abnormality”.

10.1 Troubleshooting guide

The following table shows the possible causes of and counter measures against troubles that may occur due to equipment setting errors or deterioration of consumables.
Troubles or failures due to other causes than those listed below should be serviced. As repair performed by persons who are not qualified by Olympus could cause patient or user injury and/or equipment damage, be sure to contact Olympus for repair according to Section 10.3, “Returning the endoscope for repair”.

Endoscope functions

❍ Image quality or brightness

Irregularity description	Possible cause	Solution
There is no video image.	Not all power switches are ON.	Turn ON all the power switches.
An image is not clear.	The objective lens is dirty.	Clean the objective lens with a cotton swab moistened with 70% ethyl or isopropyl alcohol.
An image is excessively dark or bright	The light source is not set properly.	Adjust the light source’s setting as described in its instruction manual.
A black point is shown in a screen.	The image guide fiber has broken.	When the image to be observed is not visible, send the endoscope to Olympus for repair.

❍ Water feeding

Irregularity description	Possible cause	Solution
The fluid is leaking from the biopsy valve.	The biopsy valve is not attached properly.	Attach it correctly.
	The syringe is not inserted securely.	Insert it securely.
The biopsy valve cannot be attached.	The biopsy valve is damaged.	Replace it with a new one.

Suction

Irregularity description	Possible cause	Solution
The suction is absent or insufficient.	The biopsy valve is not attached properly.	Attach it correctly.
	The biopsy valve is damaged.	Replace it with a new one.
	The suction pump is not set properly.	Adjust the suction pump's setting as described in its instruction manual.
	The suction valve is damaged.	Replace it with a new one.
The suction valve is sticky.	The suction valve is damaged.	Replace it with a new one.
The suction valve does not return to its original position.	The aspiration pressure is too high.	Lower the aspiration pressure.
The suction valve cannot be attached.	An incorrect suction valve is used.	Use a correct suction valve.
	The suction valve is damaged.	Replace it with a new one.

EndoTherapy accessories

Irregularity description	Possible cause	Solution
An EndoTherapy accessory does not pass through the instrument channel smoothly.	An incompatible EndoTherapy accessory is being used.	Refer to the "System chart" in the Appendix and select a compatible EndoTherapy accessory. Confirm that the color cord on the EndoTherapy accessory matches that on the endoscope.

❍ Ultrasound (display monitor image)

Irregularity description	Possible cause	Solution
Echo appears where there is no object.	Multiple echoes generated from an object with strong reflection.	Move the endoscope's distal end to another position and check to see if the echo in question moves to a greater degree than other echoes. If this happens, multiple echoes have coalesced and disturbed the ultrasonic image. Keep the endoscope's distal end away from an object with strong reflection.

❍ Balloon water feeding and aspiration

Irregularity description	Possible cause	Solution
Water feeding to the balloon and/or aspiration from the balloon does not work.	Balloon water supply channel is dirty.	Reprocess the channel.

❍ Others

Irregularity description	Possible cause	Solution
The remote switch does not work.	The wrong remote switch is operated.	Operate the correct remote switch.
	The remote switch function has been set improperly.	Set the remote switch function correctly as described in the video system center's instruction manual.

10.2 Withdrawal of the endoscope with an abnormality

If an abnormality occurs while the endoscope is in use, take a proper measure as described in either “When the endoscopic image appears on the monitor” or “When the endoscopic image does not appear on the monitor or the frozen image cannot be restored” below. After withdrawal, return the endoscope for repair as described in Section 10.3, “Returning the endoscope for repair”.

WARNING

If the endoscope cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it; leave it inside the patient and immediately contact Olympus. Forcibly withdrawing the endoscope may cause patient injury.

When the endoscopic image appears on the monitor

1. Turn OFF all equipment except the video system center, light source, monitor and suction pump.
2. When using an EndoTherapy accessory, withdraw the EndoTherapy accessory slowly while the tip of the EndoTherapy accessory is closed and/or retracted into its sheath.
3. Aspirate accumulated air, blood, mucus or other debris by depressing the suction valve.
4. Carefully withdraw the endoscope while observing the endoscopic image.
5. Remove the mouthpiece from the patient’s mouth.

When the endoscopic image does not appear on the monitor or the frozen image cannot be restored

1. Turn OFF all equipment except the video system center, light source and monitor.
2. Turn the video system center and light source OFF and then ON again. If the endoscopic image appears or the frozen image is restored, follow the procedure of step 2. in “When the endoscopic image appears on the monitor” above.
   When the endoscopic image still does not appear or the frozen image cannot be restored, perform the following steps.
3. Turn OFF the video system center, the light source and the monitor.

4. When using an EndoTherapy accessory, withdraw the EndoTherapy accessory slowly while the tip of the EndoTherapy accessory is closed and/or retracted into its sheath.
5. Turn the UP/DOWN angulation control lever to the neutral position. Release the angulation control lever and carefully withdraw the endoscope.
6. Remove the mouthpiece from the patient's mouth.

10.3 Returning the endoscope for repair

WARNING

Thoroughly clean and high-level disinfect or sterilize the endoscope before returning it for repair. Improperly reprocessed equipment presents an infection control risk to each person who handles the endoscope within the hospital or at Olympus.

CAUTION

Olympus is not liable for any injury or damage which occurs as a result of repairs attempted by non-Olympus personnel.

Before returning the endoscope for repair, contact Olympus. With the endoscope, include a description of the malfunction or damage and the name and telephone number of the individual at your location who is most familiar with the problem. Also include a repair purchase order.
When returning the endoscope for repair, follow the instructions given in "Transporting outside the hospital" on page 57.

Appendix

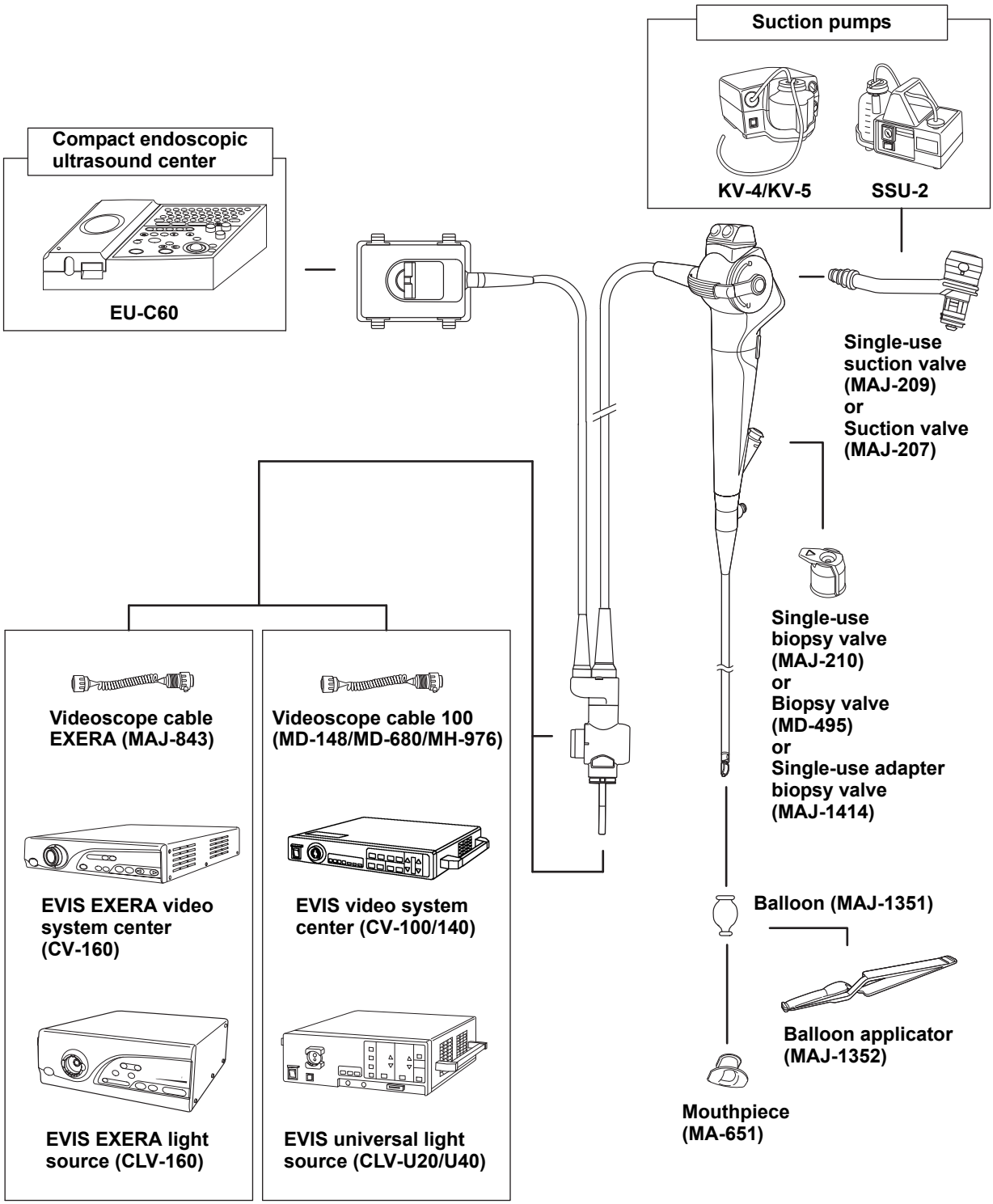
System chart

The recommended combinations of equipment and accessories that can be used with this instrument are listed below. Some items may not be available in some areas. New products released after the introduction of this instrument may also be compatible for use in combination with this instrument. For further details, contact Olympus.

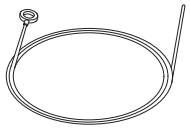
WARNING

If combinations of equipment other than those shown below are used, the full responsibility is assumed by the medical treatment facility.

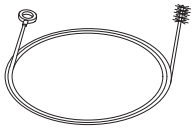
Endoscopic equipment combinations


Suction pumps
KV-4/KV-5
SSU-2
Compact endoscopic ultrasound center
EU-C60
Single-use suction valve (MAJ-209) or Suction valve (MAJ-207)
Single-use biopsy valve (MAJ-210) or Biopsy valve (MD-495) or Single-use adapter biopsy valve (MAJ-1414)
Videoscope cable EXERA (MAJ-843)
Videoscope cable 100 (MD-148/MD-680/MH-976)
EVIS EXERA video system center (CV-160)
EVIS video system center (CV-100/140)
Balloon (MAJ-1351)
Balloon applicator (MAJ-1352)
EVIS EXERA light source (CLV-160)
EVIS universal light source (CLV-U20/U40)
Mouthpiece (MA-651)

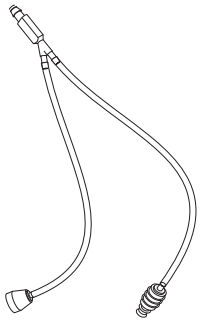
Washing and disinfection equipment



Channel cleaning wire (BW-16C)

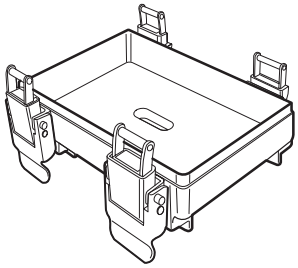


Channel cleaning brush (BW-15B)



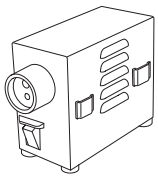
Suction cleaning adapter (MAJ-222)

Channel-opening cleaning brush (MH-507)

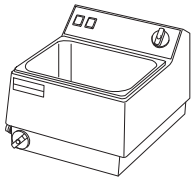


Water-resistant cap (MAJ-1057)

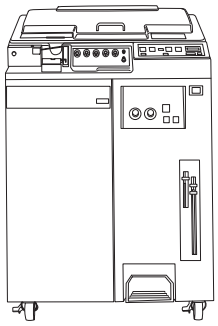
Leakage tester (MB-155)



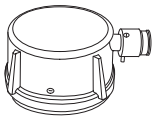
Maintenance unit (MU-1)



Ultrasonic cleaner (KS-2)

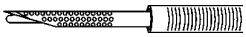
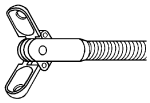


Endoscope washer (EW-30)
Endoscope reprocessor (OER)



Water-resistant cap (MH-553)

EndoTherapy accessories

	ASPIRATION NEEDLE	BIOPSY FORCEPS
	Disposable	Ellipsoid
Endoscope		
BF-UC160F-OL8	NA-201SX-4022	FB-56D-1

Inspection of the endoscope after cleaning, disinfection or sterilization in accordance with IEC 60601-2-37

After cleaning, disinfection or sterilization this instrument, check the parts or accessories that can be contaminated through contact with the patient, with body fluids, or with expired gases according to the “Method of inspection” listed below.

Inspection of the endoscope after cleaning, disinfection or sterilization

Timing of inspection	Pertinent parts, components or functions	Method of inspection
After precleaning	Waterproof	See Section 7.4, “Leakage testing” on page 80.
After cleaning, disinfection or sterilization	Inspection of the endoscope	See “Inspection of the endoscope” in Section 3.2, “Inspection of the endoscope”, on page 21.
	Bending mechanism	See “Inspection of the bending mechanism” in Section 3.2, “Inspection of the endoscope”, on page 22.
	Suction valves	See “Inspection of the suction valves” in Section 3.3, “Preparation and inspection of accessories”, on page 23.
	Biopsy valves	See “Inspection of the biopsy valves” in Section 3.3, “Preparation and inspection of accessories”, on page 25.
	Mouthpiece	See “Inspection of the mouthpiece (MA-651, optional)” in Section 3.3, “Preparation and inspection of accessories”, on page 27.
	Attaching the suction valve	See “Attaching the suction valve” in Section 3.4, “Attaching accessories to the endoscope”, on page 28.
	Attaching the biopsy valve	See “Attaching the biopsy valve” in Section 3.4, “Attaching accessories to the endoscope”, on page 29.
	Connection of the suction tube	See “Attaching the suction valve” in Section 3.4, “Attaching accessories to the endoscope”, on page 28.
	Connection of the endoscope cable	See “Connection of the endoscope and ancillary equipment” in Section 3.5, “Inspection and connection of ancillary equipment”, on page 30.
	Endoscopic image	See “Inspection of the endoscopic image” in Section 3.6, “Inspection of the endoscopic system”, on page 34.
	Water feeding function into the balloon	See “Inspection of the water feeding function into the balloon” in Section 3.6, “Inspection of the endoscopic system”, on page 36.
	Suction function	See “Inspection of the suction function” in Section 3.6, “Inspection of the endoscopic system”, on page 34.

Timing of inspection	Pertinent parts, components or functions	Method of inspection
After cleaning, disinfection or sterilization	Instrument channel	See “Inspection of the instrument channel” in Section 3.6, “Inspection of the endoscopic system”, on page 35.
	Ultrasonic image	See “Inspection of the ultrasonic image” in Section 3.6, “Inspection of the endoscopic system”, on page 37.
	Balloon	See Section 3.7, “Preparation and inspection of the balloon” on page 38.

About the acoustic output table

Acoustic Output Information in Accordance with the FDA Guidance: "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers"

The terms used in the acoustic output table are as follows:

Transducer model is the Olympus EUS EXERA ultrasonic gastrovideoscope model.

$I_{SPTA.3}$ is the derated spatial peak, temporal average intensity in milliWatts/cm^2.

TI type is the applicable thermal index for the transducer, imaging mode, and exam type.

TI value is the thermal index value for the transducer, imaging mode, and exam type.

MI is the mechanical index.

$I_{pa.3}$@MImax in W/cm^2 is the derated pulse average intensity at the maximum MI.

Acoustic output table

Transducer model	$I_{SPTA.3}$	TI type	TI value	MI	$I_{pa.3}$@MImax
BF-UC160F-OL8	50	TIc	0.3	0.58	76.38

Global maximum derated I_{SPTA} and MI values

The following values represent worst-case values of the $I_{SPTA.3}$ and MI for each transducer and each mode, and over-all operating conditions for that mode. These tables fulfill the requirements of Appendix G, Section C2, of the September 30, 1997 FDA document, "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers".

Transducer model	Imaging mode	$I_{SPTA.3}$	MI
BF-UC160F-OL8	2D	14	0.58
	Color power doppler	50	0.56

Acoustic measurement precision and uncertainty

All table entries have been obtained at the same operating conditions that give rise to the maximum index value in the first column of the table. Measurement precision and uncertainty for power, pressure, intensity, and other quantities that are used to derive the values in the acoustic output table are shown in the table below. In accordance with Section 6.4 of the output display standard, the following measurement precision and uncertainty values are determined by making repeat measurements and stating the standard deviation as a percentage.

Quantity	Precision (% of standard deviation)	Uncertainty (95% confidence)
Pr	5.4%	±15%
$Pr_{.3}$	5.4%	±15%
Wo	6.2%	±19%
Fc	< 1%	±4.5%
PII	3.2%	+21% to −24%
$PII_{.3}$	3.2%	+21% to −24%

Acoustic Output Information Accordance with IEC 60601-2-37

BF-UC160F-OL8 will not exceed a MI (mechanical index) of 1.0, or an $I_{zpta,\alpha}(z)$ (attenuated spatial-peak temporal-average intensity) of 720 mW/cm^2 in any mode. In addition, BF-UC160F-OL8 will not exceed a TI (thermal index) of 1.0 in any mode.

EMC information

This model is intended for use in the electromagnetic environments specified below. The user and the medical staff should ensure that it is used only in these environments.

❍ Magnetic emission compliance information and recommended electromagnetic environments

Emission standard	Compliance	Guidance
RF emissions CISPR 11	Group 1	This instrument uses RF (Radio Frequency) energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiated emissions CISPR 11	Class A	This instrument is equipment suitable for use in all establishments, other than domestic establishments and those directly connected to a low voltage power supply network that supplies buildings used for domestic purposes.
Main terminal conducted emissions CISPR 11		
Harmonic emissions IEC 61000-3-2	Class A	This instrument's harmonic emissions are low and are not likely to cause any problem in the typical commercial power supply connected to this instrument.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	This instrument stabilizes its own radio variability and has no affect such as flicker in lighting apparatus.

❍ Electromagnetic immunity compliance information and recommended electromagnetic environments

Immunity test	IEC 60601-1-2 test level	Compliance level	Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ±2, ±4, ±6 kV Air: ±2, ±4, ±8 kV	Same as left	Floors should by be made of wood, concrete, or ceramic tile that hardly produces static. If floors are covered with synthetic material that tends to produce static, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Same as left	Mains power quality should be that of a typical commercial (original condition feeding the facilities) or hospital environment.
Surge IEC 61000-4-5	Differential mode: ±0.5, ±1 kV Common mode: ±0.5, ±1, ±2 kV	Same as left	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle	Same as left	Mains power quality should be that of a typical commercial or hospital environment. If the user of this instrument requires continued operation during power mains interruptions, it is recommended that this instrument be powered from an uninterruptible power supply or a battery.
	40% U_T (60% dip in U_T) for 5 cycle		
	70% U_T (30% dip in U_T) for 25 cycle		
	< 5% U_T (> 95% dip in U_T) for 5 seconds		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Same as left	It is recommended to use this instrument by maintaining enough distance from any equipment that operates with high current.

NOTE

U_T is the AC mains power supply prior to application of the test level.

❍ Cautions and recommended electromagnetic environment regarding portable and mobile RF communications equipment such as cellular phones

Immunity test	IEC 60601-1-2 test level	Compliance level	Guidance
			Formula for recommended separation distance (V_1=E_1=3 according to the compliance level)
Conducted RF IEC 61000-4-6	3 Vrms (150 kHz – 80 MHz)	3 V (V_1)	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m (80 MHz – 2.5 GHz)	3 V/m (E_1)	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz – 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz – 2.5 GHz

NOTE

- Where “P” is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and “d” is the recommended separation distance in meters (m).
- This instrument complies with the requirements of IEC 60601-1-2: 2001. However, under electromagnetic environment that exceeds its noise level, electromagnetic interference may occur on this instrument.
- Electromagnetic interference may occur on this instrument near a high-frequency electrosurgical equipment and/or other equipment marked with the following symbol:

❍ Recommended separation distance between portable and mobile RF communications equipment and this instrument

Rated maximum output power of transmitter P (W)	Separation distance according to frequency of transmitter (m) (calculated as V_1=3 and E_1=3)		
	150 kHz – 80 MHz	80 MHz – 800 MHz	800 MHz – 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

NOTE

The guidance may not apply in some situations.
Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
Portable and mobile RF communications equipment such as cellular phones should be used no closer to any part of this instrument, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

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